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QUALITY CONTROL ASSESSMENT OF THE COMMERCIALLY AVAILABLE AMLODIPINE TABLET BRANDS IN PORT HARCOURT, NIGERIA

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ABSTRACT

Background: Hypertension remains a major public health challenge in Nigeria and globally, with calcium channel blockers such as amlodipine forming a cornerstone of long-term pharmacotherapy. The therapeutic effectiveness of amlodipine tablets depends on their compliance with established pharmacopeial quality control parameters. Concerns about substandard and falsified medicines in low- and middle-income countries necessitate continuous post-market quality surveillance of commercially available brands.

Objectives: This study aimed to assess the quality control parameters and pharmaceutical equivalence of selected commercially available amlodipine tablet brands marketed in Nigeria in order to ascertain their compliance with official specifications.

Methods: Multiple brands of amlodipine tablets were procured from registered pharmacies. Standard physicochemical quality control tests were performed in accordance with pharmacopeial guidelines, including visual inspection, weight uniformity, hardness, friability, disintegration time, assay of active pharmaceutical ingredient (API) content using validated analytical methods, and in vitro dissolution studies. The dissolution profiles were evaluated against pharmacopeial acceptance criteria to determine interchangeability and compliance.

Results: All evaluated brands complied with official specifications for organoleptic properties and weight uniformity. Most brands met acceptable limits for hardness, friability, and disintegration time. Assay results demonstrated that the API content of the majority of brands fell within the pharmacopeial range (typically 90–110%). Dissolution testing revealed that while several brands achieved the required percentage drug release within the stipulated time, minor variations in release profiles were observed among some brands.

Conclusion: The findings indicate that most commercially available amlodipine tablet brands assessed were of acceptable pharmaceutical quality and complied with established standards, supporting their therapeutic interchangeability. Continuous regulatory surveillance remains essential to ensure sustained product quality and patient safety.

KEYWORDS: Amlodipine, Quality control, Pharmaceutical equivalence, Dissolution profile, Post-market surveillance.

INTRODUCTION

There is increasing numbers of generic drug products available in the market. This makes it possible for healthcare workers to select a particular generic drug from several equivalent products.[1] Internationally, statistics shows that innovator drug products are traditionally and drastically prescribed, giving rise to a high cost of drug budgets. Since the use of generic drugs provides a lower cost than the innovator or branded products, great savings in healthcare payment can be made. Generic drugs are usually considerably prescribed in many countries because they are cost-effective making them easy for patients to afford. Many countries have witnessed a drastic increase in generic drugs prescription

because it has been observed that they are usually pharmaceutically and therapeutically equivalent to the innovator or branded products. Take for example, in 1975, the number of generic drugs prescribed in the United States was about 9% of the total drugs prescribed.[2]

In order to help reduce cost of treatment while still maintaining quality healthcare service provision and good patient outcome, the number increased to about 20% in 1984 and to 40% in 1991. These generic drugs are usually manufactured by different pharmaceutical firms and there have been some observed differences in the pharmaceutical activities of these products and its variable dosage forms. Also, availability of counterfeit drugs in most poor/developing countries has been widely noticed with generic drugs and this has also led to reduction in therapeutic effects of the generic drug product and consequently loss of public trust on some of these generic products.[3]

Empirical evidence found that generic drugs have lower therapeutic effectiveness as opposed to branded products though, they are bio-equivalents of their innovative peers and are produced under good manufacturing practices.[4-6]

The manufacturers of generic drugs need FDA approval before the marketing of their drug products. To obtain FDA approval for a generic drug, it must match the innovator drug in active ingredients, strength, dosage form, route of administration, the same usage indications, bioequivalent meet, batch requirements for identity, purity, quality and be manufactured in accordance with the strict standards of FDA's good manufacturing practice regulations required for innovative products.[7]

In Nigeria, the pharmaceutical market is characterized by a high prevalence of multisource (generic) medicines. While generic substitution improves affordability and accessibility, concerns have been raised regarding the quality, pharmaceutical equivalence, and bioequivalence of some marketed brands. Studies conducted in different regions of Nigeria have reported variability in physicochemical parameters of amlodipine tablets. Olayemi et al. found that although several brands complied with basic pharmacopeial requirements, only half met dissolution specifications within the recommended time frame, indicating possible inconsistencies in drug release performance.[8]

Similarly, Igboasoiyi et al. reported variability among ten brands evaluated in Uyo, with differences observed in assay and in vitro quality parameters, though most complied with compendial limits.[9]

More recent nationwide surveillance under the EQUIMEDS study demonstrated that a proportion of generic antihypertensive medicines in Nigeria were substandard with respect to active pharmaceutical ingredient content, emphasizing the need for continuous post-market quality monitoring.[10] In response to such concerns, the National Agency for Food and Drug Administration and Control (NAFDAC) has intensified risk-based post-market surveillance between 2021 and 2023, identifying instances of non-compliance with regulatory standards among selected medical products.[11]

Quality control assessment of amlodipine tablets typically involves evaluation of organoleptic properties, uniformity of weight, hardness, friability, disintegration time, assay of active ingredient, and dissolution testing in accordance with pharmacopeial specifications such as those of the United States Pharmacopeia (USP) and British Pharmacopoeia (BP). Dissolution testing is particularly critical, as it serves as a surrogate indicator of in vivo bioavailability and therapeutic performance. Failure to meet dissolution or assay standards may result in subtherapeutic plasma concentrations, poor blood pressure control, and increased cardiovascular risk. Port Harcourt, a major urban and commercial hub in Rivers State, Nigeria, has a diverse pharmaceutical retail sector with multiple brands of amlodipine tablets available through community pharmacies and patent medicine vendors. Given the high burden of hypertension in urban populations and the wide availability of different generic brands, systematic quality control assessment of amlodipine tablets marketed in Port Harcourt is essential. Such evaluation will provide evidence regarding their compliance with pharmacopeial standards, ensure therapeutic interchangeability, and support regulatory decision-making.

MATERIALS AND METHODS

Materials

Collection of Materials

A commercial survey was carried out across various regions in Nigeria to ascertain the lines of amlodipine besylate tablets brands marketed in Nigeria. Ten commercial brands of amlodipine, labelled to contain 10mg per tablet, from different manufacturers were procured from various pharmacy outlets in Nigeria. The study drug comprises, the test drug samples (generic brands) and reference drug sample (innovator brand) and coded as A, B, C, D to J. The table below summarizes different brands that were sourced and utilized for this work.

Table 1: Brands of Amlodipine used for the study, batch A – C.

BRAND CODE	BRAND NAME	MANUFACTURED BY	MARKETED BY	COUNTRY OF ORIGIN	INSCRIPTION	LABELLED STRENGTH (mg)	BATCH/LOT NUMBER	NAFDAC REG. NUMBER	MANUFACTURED DATE	EXPIRY DATE
A	Norvasc®	Pfizer Pharma.	Pfizer Pharma	USA	AML-10 Pfizer	10	HF8884	04-5354	FEB.-2023	JAN.-2025
B	Amlodipine 10mg ™	Scott-Edil Pharmacia Ltd.	Pocco Pharma. Ltd.	India	Scored	10	XT3J004	B4-6505	OCT.-2023	SEP.-2026
C	Amlodipine ™	Teva UK Ltd.	Teva UK Ltd.	United Kingdom	A 10 Scored	10	7500623	-	-	JUN.-2028

Table 2: Brands of Amlodipine used for the study, batch D – J.

BRAND CODE	BRAND NAME	MANUFACTURED BY	MARKETED BY	India	INSCRIPTION	LABELLED STRENGTH (mg)	BATCH/LOT NUMBER	NAFDAC REG. NUMBER	MANUFACTURED DATE	EXPIRY DATE
D	Amlodipine ™	IMPULSE PHARMA PVT. LTD.	EDEN U-K PHARM LTD.	India	A 10	10	2308034	B4-6762	AUG.-2023	JUL.-2026
E	Amlodipine ™	ALPA LABORATORIES LTD.	CHEZ RESOURCES PHARMA NIG LTD.	Nigeria	AB 10 Scored	10	TE3276	B4-9954	OCT-2023	SEP.-2026
F	Drulovask ®	DRUGFIELD PHARMACEUTICALS LTD.	DRUGFIELD PHARMACEUTICALS LTD.	Nigeria	DGF Scored	10	160L0128	A11-100104	NOV-2023	OCT.-2028
G	Emzovasc ®-10	Emzor Pharmaceutical Industries Ltd.	Emzor Pharmaceutical Industries Ltd.	India	EMZOR Scored	10	S07407SC	B4-3303	DEC.-2023	DEC.-2026
H	Amlodipine 10 mg™	Vapi Care Pharma Ltd.	Swipha	Nigeria	10	10	VGT 230075	A4-2279	APR.-2023	MAR.-2026
I	Amlovar®	NEIMETHINT`L PHARMACEUTICALS PLC.	NEIMETH INT`L PHARMACEUTICALS PLC.	India	PG1 10 N	10	10105045	A4-0333	FEB.-2023	JAN.-2025
J	Amlong-10	MICRO LABS LTD	ELBE PHARMA NIGERIA LTD.		AM 10/ Scored	10	ABGH0069	A4-0445	APR.-2023	MAR.-2026

An industrial grade Amlodipine besylate pure sample was sourced from India.

Equipment, Apparatus and Solvent
Analytical weighing balance, (Kern and Shon GmbH/ Germany), Monsanto Hardness tester (Bexco/USA), Friabilator (Erweka, Germany), Micrometer screw-gauge, Volumetric flasks (10 & 100 ml), Measuring Cylinders (50 &1000 ml) (Pyrex/USA; Minghe/China), Disintegration apparatus & DT60 Dissolution tester (Erweka, Heusenstamm/ Germany), UV spectrophotometer (), Pipette, Mortar and pestle, Thermometer, Whatmann's filter paper (25 mm), 0.1N Hydrochloric acid (HCl) and Distilled water.

METHODS

Weight Uniformity Test

Weight uniformity test was performed on different brands of Amlodipine besylate tablets as described in the British pharmacopoeia, 2005. Twenty (20) tablets were selected at random per batch and weight of each tablet was taken using an analytical weighing balance. The mean (average) weight of the twenty (20) Amlodipine besylate tablets and standard deviation were statistically calculated and recorded.

Hardness Test

Ten (10) tablets each from the ten brands were tested using a Monsanto hardness tester. The crushing strength in kg/m^2 for each tablet was obtained and recorded. The mean hardness and the standard deviation were statistically calculated and recorded.

Friability Test

Ten (10) tablets were dusted and weighed (W1) prior to testing and subjected to a uniform tumbling motion for a period of 4 minutes at 25 revs/min in a fixed geometry closed chamber called a friabilator. They were then dedusted and reweighed (W2). From the results obtained, weight lost was calculated and expressed in percentage.

Thickness Test

The thickness of the brands of Amlodipine was each obtained by measuring the thickness of 10 tablets from each brand using a micrometer screw-gauge. The values obtained in mm were recorded and used to compare against standard values.

Disintegration Test

The ERWKA disintegration test apparatus was used based on the British Pharmacopoeia 2005 method. The disintegration medium vessel was filled with 0.1N HCL to 900 ml and temperature maintained at 37±1°C all through the testing process. Six (6) tablets of each product were selected and placed separately on the six cylindrical tubes of the basket, and a disc was placed to act as a stopper. The time taken for each tablet to completely disintegrate and pass through the net into the disintegration medium was recorded and inferences made.

Preparation of Standard Stock Solution

A 100 mg of the pure sample of Amlodipine besylate was completely dissolved in 100 ml of 0.1N HCl maintained at a pH 1. A stock solution with a concentration of 1mg/ml of pure Amlodipine besylate was thus prepared.

Determination of Absorbance Maximum and Beer-Lambert's Curve

From the stock, aliquot of 0.1 ml, 0.5 ml, 1.0 ml, 1.5 ml, and 2.0 ml were respectively measured out using a pipette and transferred to previously rinsed 10 ml volumetric flasks. They were them made up to 10 ml to obtain concentrations of between 0.01 mg/ml and 0.20 mg/ml. The optimum wavelength/absorption maxima of 364 nm were selected and recorded.

The samples were then analyzed using a UV spectrophotometer at a set wavelength of 364 nm. The values gotten were then used to determine the Beer's plot and calibration curve obtained.

Content of Active Ingredient Test

Twenty (20) tablets for each batch were randomly selected, weighed using an analytical weighing balance and their average weight equivalent to the weight of one tablet calculated. The tablets were then crushed in a mortar and pestle until a smooth powder was gotten. The average weight which is equivalent to the average theoretical content (10 mg) of each tablet was then weighed out from the crushed sample. The weighed sample was then dissolved in 100 ml of 0.1 N HCl acid to get a stock solution with a concentration of 1 mg/ml, the solution was then filtered using the non-absorbent filter paper. A 0.1 ml of the filtrate was withdrawn and transferred to a 10 ml volumetric flask, it was made up to 10 ml using 0.1 N HCl acid.

The diluted samples for each batch were then analyzed using a UV spectrophotometer at 364 nm. The obtained values were used to calculate the actual content of active ingredient of the different brands.

Dissolution Test

The dissolution rate tests were carried out on the different brands of Amlodipine besylate tablets using USP apparatus 2 (DT60 dissolution tester, Erweka, Heusenstamm, Germany). A 900 mL volume of 0.1 N HCl acid maintained at a temperature of 37 ± 0.5 ^{O}C was used. The rotation speed of the paddles was set at 50 rpm. 5mL volumes of the samples were withdrawn at 2, 5, 10, 15, 20, 25, 30, 40, 50 and 60 minutes respectively by a an already calibrated pipette. After withdrawal of the sample, fresh dissolution medium was simultaneously replaced in the vessel to maintain a constant dissolution volume. The collected samples were filtered and 1 ml was transferred to a volumetric flask and made up to 10 ml with 0.1 N HCL acid. The actual concentration of the different batches was then determined using a UV spectroscopy at a wavelength of

364 nm. Using the standard curve already prepared, the percentage of drug released was determined for the tablets.

Model-independent

Model-independent was also employed for this comparison using the percentage drug released. The methods used include: Similarity factor (*f*2), Difference factor (*f*1) and Dissolution efficiency (DE%).

Ethical Consideration

For the purpose of confidentiality, the brand names of the drugs used for the study were withheld and were represented rather with codes such as (batch A, batch B, batch C, batch D to batch J, which respectively represent, the test and reference drug samples).

Statistical Analysis

The research data obtained were statistically analyzed using the following statistical software; Microsoft Excel, version 2016 and Statistical package for social sciences (SPSS), version 23.

RESULTS

Results of the physicochemical parameters of different brands of Amlodipine besylate.

Table 3 and 4 show the Physicochemical parameters of different brands of amlodipine besylate tablet collected from various pharmacy retail outlets in Port Harcourt, Nigeria, coded batches A to J.

Table 3: Physicochemical parameters of different brands of amlodipine besylate tablet batches A to D.

Brand co Code	Colour	Shape	Weight Uniformity (mg) ± SD N=20	Thickness (mm) ± SD N=10	Diameter (mm) ± SD N=10	Hardness (Kg/cm) ± SD N=10	Friability (%) N=10	Disintegration Time(min) ± SD N=6
A	White	Octagon	349.8 ± 8.9	3.0 ± 0.0	1.2 ± 0.0	5.7 ± 0.5	0.25	17:39 ± 0.05
B	White	Round	407.6 ± 4.7	3.0 ± 0.0	1.0 ± 0.0	3.6 ± 1.2	0.28	4:20 ± 0.09
C	White	Round	187.0 ± 2.7	3.0 ± 0.0	1.1 ± 0.0	1.3 ± 0.3	0.20	3:00 ± 0.06
D	White	Round	410.4 ± 4.3	1.5 ± 0.0	0.8 ± 0.0	2.3 ± 0.5	0.37	3:23 ± 0.05

Table 4: Physiochemical parameters of different brands of amlodipine besylate tablet, batches E to J.

Brand Code	Colour	Shape	Weight Uniformity (mg) ± SD N=20	Thickness (mm) ± SD N=10	Diameter (mm) ± SD N=10	Hardness (Kg/cm) ± SD N=10	Friability (%) N=10	Disintegration Time(min) ± SD N=6
E	White	Round	235.0 ± 0.0	2.0 ± 0.0	1.1 ± 0.0	2.3 ± 0.5	0.22	7:30 ± 0.08
F	Orange	Oval	142.8 ± 4.6	3.0 ± 0.0	0.5 ± 0.0	4.9 ± 0.9	1.23	3:47 ± 0.04
G	White	Round	134.0 ± 0.9	2.0 ± 0.0	0.7 ± 0.0	4.4 ± 0.5	0.07	2:15 ± 0.06
H	White	Round	401.5 ± 18.1	2.0 ± 0.0	0.7 ± 0.0	2.9 ± 0.2	0.87	8:50 ± 0.01
I	White	Hexagon	190.3 ± 3.2	4.0 ± 0.0	1.1 ± 0.0	5.2 ± 0.4	0.17	7:07 ± 0.05
J	White	Round	407.6 ± 2.4	2.0 ± 0.0	0.8 ± 0.0	6.0 ± 0.4	0.05	2:53 ± 0.05

This research is based on ten (10) different brands of Amlodipine besylate tablets, randomly selected (procured) from registered pharmacies in the southern part of Nigeria, with their detailed information on table 1 and table 2. Hence, all of the sampled tablets were either round or oval in shape, and had a declared dose expressed as Amlodipine besylate 10 mg. The quality control tests for tablet dosage forms are usually categorized into pharmacopoeia and non-pharmacopoeia tests. The non-pharmacopoeia test includes, the organoleptic tests, thickness, diameter, hardness and friability. These non-pharmacopoeia test have no standardized prescribed limit thus different manufacturers set the limit for their products. The colours (organoleptic property) of samples under study (Table 3 and 4) range from white to orange.

The tablet thickness is an important characteristic in packing operations and in counting of tablets where the machine depends on the thickness of the tablets.[12] The tablet thickness is determined by the diameter of the die, the amount of fill permitted to enter the die cavity, the compaction characteristics of the fill material and the force applied during compaction.[13] The result of this study on Table 3 and 4 shows that all the tested samples pass the thickness test since most literature prescribed that the thickness should be controlled within ± 5% variation of the individual tablet average thickness.[13]

In furtherance to the quality assessment of the samples under study, hardness test was also carried out, otherwise called crushing test. Crushing force is the force required to break a tablet in a diametric compression test. Tablets are expected to be hard enough to withstand pressure from handling, shipping and distribution, yet soft enough to be disintegrated after being swallowed. Hardness can affect the disintegration, if the tablet is too hard, it may not disintegrate within the required period of time and if the tablet is too soft, it may not be able to withstand handling during subsequent processing such as coating or packaging.[14] The minimum hardness a tablet is expected to maintain, is 4 kg force while the maximum force is 8

kg.[15] However, it can be deduced that the hardness of the tablet depends on both the force of compression and the mass of the granules compressed, and there is a direct relationship between the applied force and both the mass and the radius of the compressed tablet. Sometimes, test samples may fail to meet the prescribed force due to the compressional force applied when compressing the tablet, the characteristics of the granules to be compressed, the amount and type of binder and/or lubricant used, granulation method adopted in preparing the tablet and the space between the upper and lower punches at the time of compression.[16] It must be stated that hardness test alone is not enough parameter to reject a batch, the rejection of a batch can only be valid if the hardness test results is combined and compare with that of disintegration test to ascertain how tablet hardness has influenced the tablets disintegration.

Friability is a phenomenon where the surface of the tablet damages or shows a site of damage due to mechanical impact. The friability test is performed to determine the ability of tablets to withstand abrasion during packaging, handling, distribution, and shipping processes. Pharmaceutically, the reason behind this test is to mimic the kind of forces caused by phenomena, such as collisions and sliding of tablets towards each other, which a tablet is subjected to during coating, packaging, handling and shipping. The USP specification for friability test is a percentage loss not greater than 1% and the test is also rejected if any tablet caps, laminates or break up in the course of the test. From the result (Table 1 and 2), batch F has a %friability value of 2.3%, it failed the test. Tablets friability can be influenced by the moisture content of the tablet granulation in the finished tablets. A low but acceptable moisture level frequently comes in as a binder incorporated by wet gum granulation process. Very dry granulation that contain only fractional percentages of moisture will often produce more friable tablets than will granules containing 2 to 4% moisture.[14]

Uniformity of weight of a drug is important because it ensures that every tablet contains the amount of drug substance intended, with little variation among tablets within a batch. The weight variation of individual tablet is a valid indication of the corresponding variation in the drug content. With the exception of sample batch C, E, F, G and I whose average weight is less than 250 mg although more than 80 mg (the limit of which is 7.5%), the remaining samples had an average weight of 250 mg or more. when weighed singly, the samples were not expected to have more than two of the tablets deviating from the average weight by a percentage greater than ±5% and none should deviate by more than twice that percentage. The above result (Table 3 and 4) showed that all the samples complied with the standard limit stipulated above.

The rate of drug absorption as well as the therapeutic efficacy of the drug is dependent upon the disintegration time. The disintegration time is one of the measures of the drug quality, if the disintegration time is too high, it may imply that the force of compression is too high, among other reasons. An inconsistent disintegration time within a batch could imply lack of uniformity within the batch. According to USP, 2013 specifications, the disintegration time should be less than 30 minutes for film coated tablets. From the results table 3 and 4, all the samples pass the test according to the result despite the fact that with exception of sample A with a higher disintegration time (17.39 min). Factors such as the type and concentration of binder used, method of incorporation, the presence of excessive and overly mixed lubricant, and compression force may affect the way tablets disintegrate.[15]

The Beer Lambert`s plot

In this study, sample quantification was based on the previously constructed calibration curve. The calibration curve has correlation coefficient (r) of 0.7176 and linear equation (y) of 0.7176. It is linear in the ranges of 0.09 – 0.12 mg/ml.

Figure 1 shows the Standard calibration curve for the pure Amlodipine besylate.

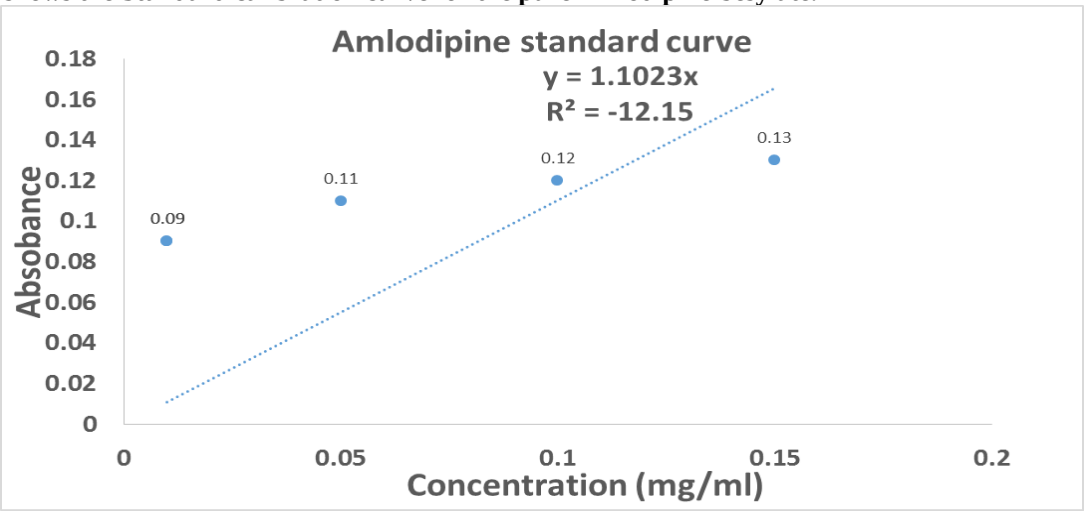

Figure 1: Standard calibration curve for pure Amlodipine besylate.

Results of the Amlodipine besylate test drug samples and reference drug sample assay

Figure 2 shows the Percentage of active content of different brands of Amlodipine besylate tablets in Port Harcourt Nigeria.

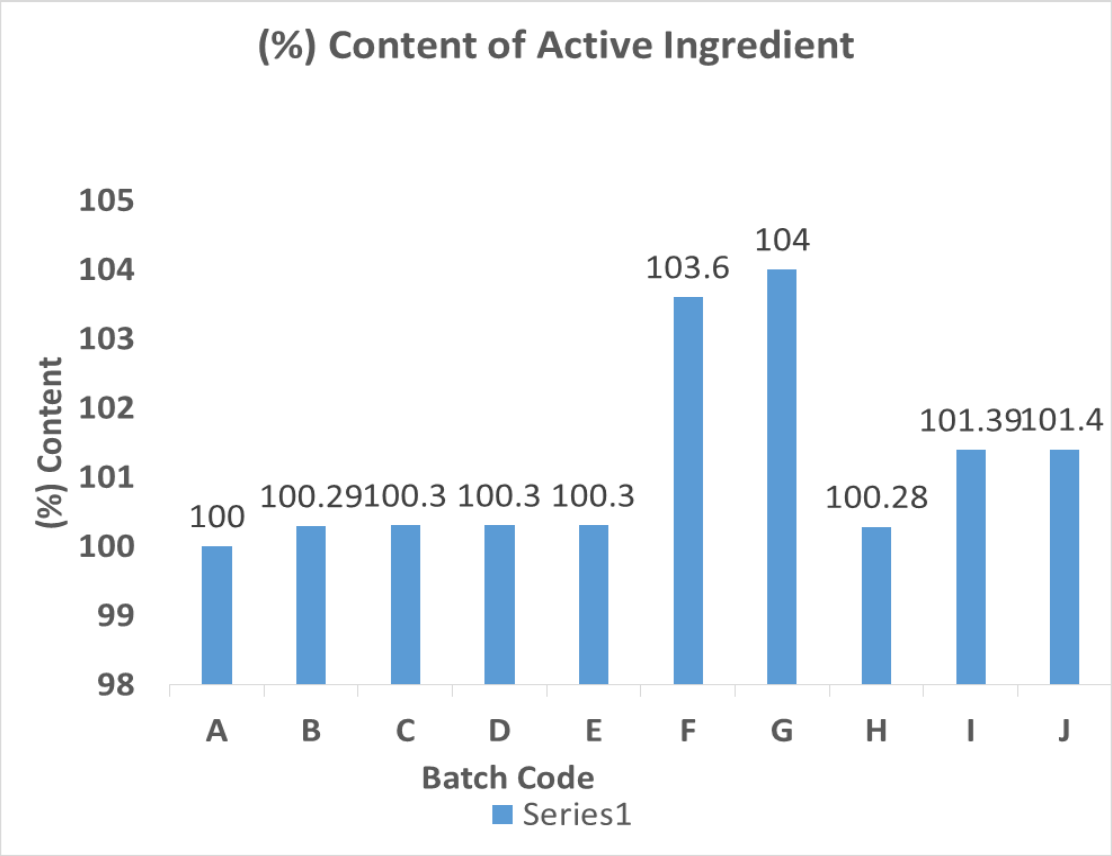

Figure 2: Percentage of active content of different brands of Amlodipine besylate tablets marketed in Port Harcourt, Nigeria.

The content of active ingredient is an important quality measure of the final solid dosage form of drug product. This assay ensures that a consistent dose of the active pharmaceutical ingredients (API) is maintained between batches so that the patient receives the correct dose. The active ingredient needs to be evenly distributed throughout the tablet to ensure that if the tablet is split into half, each half of the tablet has an equal dose.[17]

According to the USP specification, the requirement for content uniformity is met if the amount of active ingredient in nine (9) of the ten (10) tablets lies between the range of 75% - 125% of the label claim. From the result obtained (Table 3.2), all the samples under the study pass the test. The failure of sample F to pass this test may be as a result of uneven distribution of the drug in the powder/granules or segregation of the powder mixture in granulation during formulation processes.

Results of the drug bioequivalence studies of nine generic brands of Amlodipine besylate tablet 10 mg in comparison with the innovator brand of same study drug

Table 2 shows the dissimilarity factor *(f1)* and similarity factor *(f2)* of each brand of Amlodipine besylate tablet 10 mg with respect to the innovator brand, batch A.

Table 6: Dissimilarity factor *(f1)* and similarity factor *(f2)* of each brand of Amlodipine besylate 10 mg with respect to the innovator brand batch A.

Pair Comparison	*f2*	*f1*
B vs A	65.90	6.62
C vs A	63.50	8.37
D vs A	63.50	7.67
E vs A	54.20	20.14
F vs A	3.74	-1.24
G vs A	62.86	8.89
H vs A	54.61	19.34
I vs A	81.76	1.31
J vs A	17.99	-1.82

Table 6 shows the Dissimilarity Factor *(f1)* and Similarity Factor *(f2)* of each Brand of Amlodipine Besylate Tablet 10 mg with respect to the Innovator Brand, Batch A.

The statistical comparison of the profiles was carried out. In order to evaluate both dissimilarity and the similarity

factors between test and reference dissolution profiles, both *f*1 and *f*2 were calculated. Only if the test samples showed a similarity factor (*f*2) higher than 50% and a dissimilarity factor (*f*1) less than 15% in the medium, then it can be predicted as a successful bioequivalence profile of the product. As shown in Table 3, the *f*1 values for samples A, B, C, D, F, and G were less than 15 while *f*1 values for samples E, and H were greater than 15. But the closer the *f*1 value is to zero value the lesser the dissimilarity between the product, thus sample F, J and I with the lowest value of *f*1, -1.24, -1.82 and 1.31 respectively, are most similar to the innovator product in terms of dissolution profile than any of the remaining samples. Seven batches have *f*2 values greater than 50 (samples batches I, B, C, D and G) and eight *f*2 values were lower than 50 (batches F and J). Therefore, the *f*1 and *f*2 values for sample batches I, B, C, D and G seemed to support dissolution profile similarity with innovator product "batch A". Based on the results from this study we can say that only five brands of Amlodipine besylate tablets (I, B, C, D and G) out of the nine generic brands showed similarity to the innovator brand (sample A) and therefore these five generic brands can be interchanged with the innovator product.

Results of the dissolution Efficiency (%DE) of each brand of Amlodipine besylate tablets 10 mg

Table 7 shows the dissolution efficiency (% DE) of each brand of Amlodipine besylate tablet 10 mg.

Table 7: Dissolution Efficiency (%DE) of each brand of Amlodipine besylate tablet 10 mg.

Batch Code	%DE	Δ %DE
A	99.90	-
B vs A	93.29	-6.61
C vs A	91.54	-8.36
D vs A	92.23	-7.66
E vs A	79.78	-20.12
F vs A	101.14	1.24
G vs A	91.02	-8.88
H vs A	80.58	-19.32
I vs A	98.59	-1.31
J vs A	101.72	1.82

Table 7 shows the dissolution efficiency (% DE) of each brand of Amlodipine besylate tablet 10 mg. Δ %DE = Test product – Reference product.

The Dissolution Efficiency (DE) is defined as the area under the dissolution curve up to a certain time, t, expressed as a percentage of the area of the rectangle described by 100% dissolution in the time.[18] The reference and test product can be said to be equivalent if the absolute difference between their dissolution efficiencies is within appropriate limits (±10%, which is often used).[19] All the samples had dissolution efficiency (Table 7) greater than 70% and therefore could be considered quality products. However, comparing the % DE, it can be seen that the values obtained for samples A - J were less than 10 making the brands similar to the innovator brand batch A, and thus therapeutically, they can be interchangeably used with the innovator brand, sample A.

Results of the Fourier Transform InfraRed Spectroscopy (FTIR) of each brand of Amlodipine besylate tablets

Figures 3 – 13 shows the FTIR of Amlodipine besylate tablets, batches A – j, and the FTIR of the pure sample of the study drug sample.

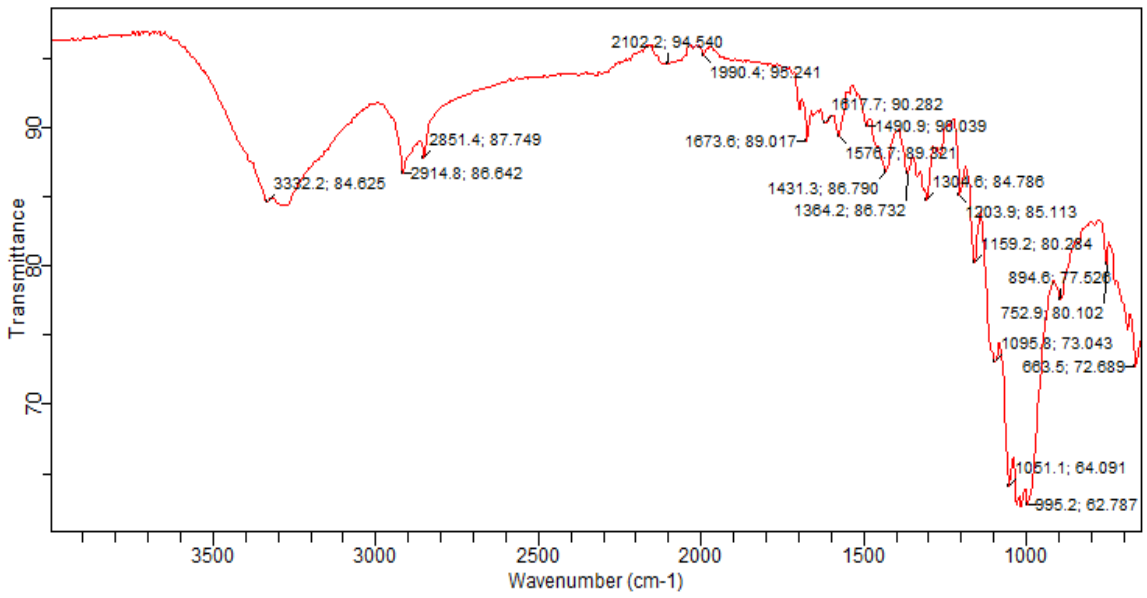

Figure 3: FTIR for batch A.

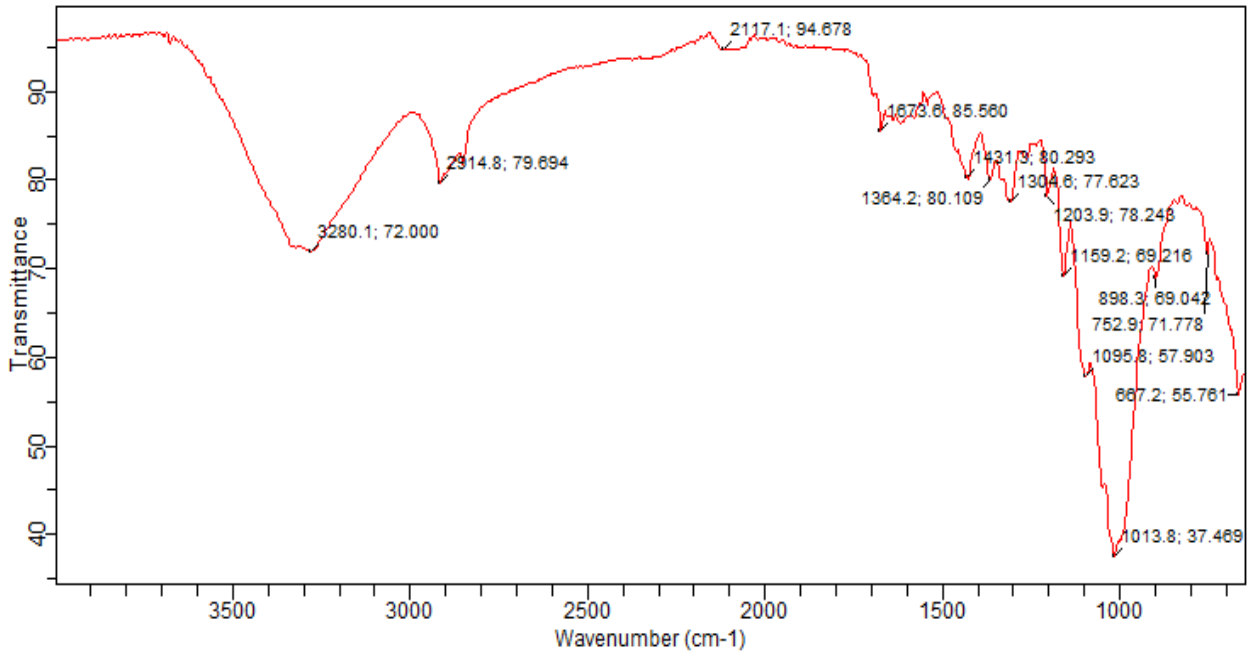

Figure 4: FTIR for batch B.

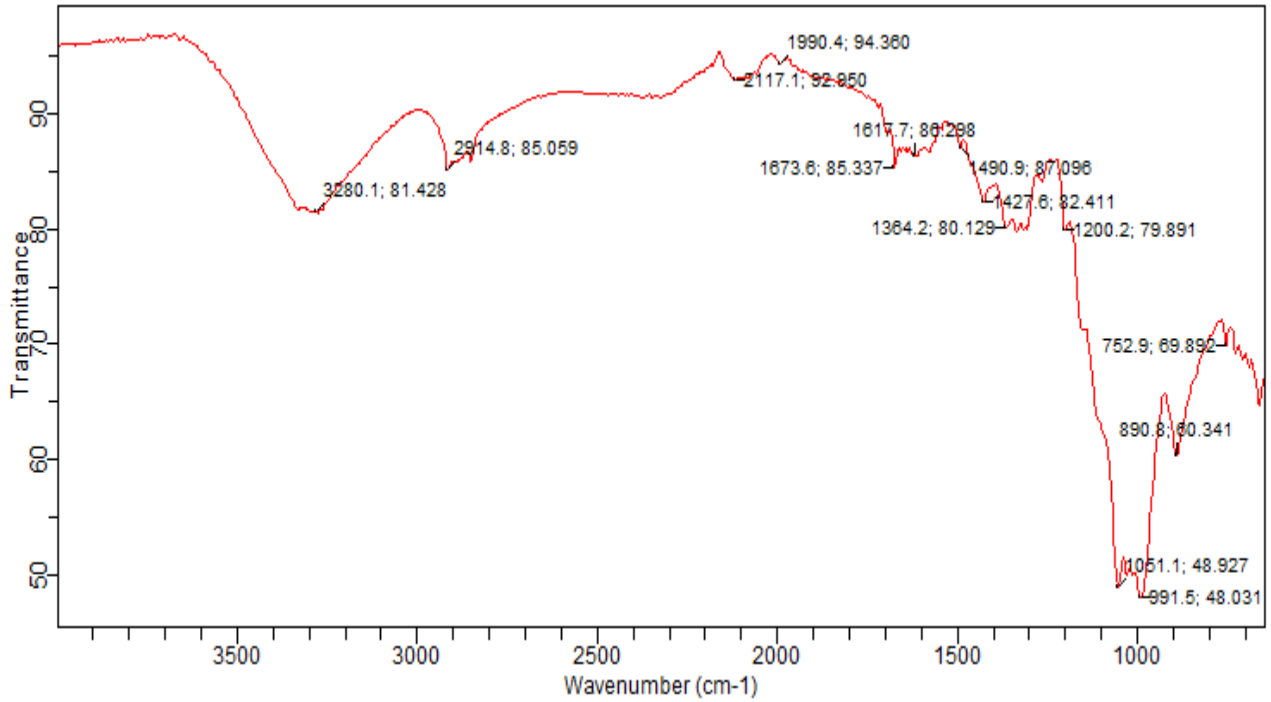

Figure 5: FTIR for batch C.

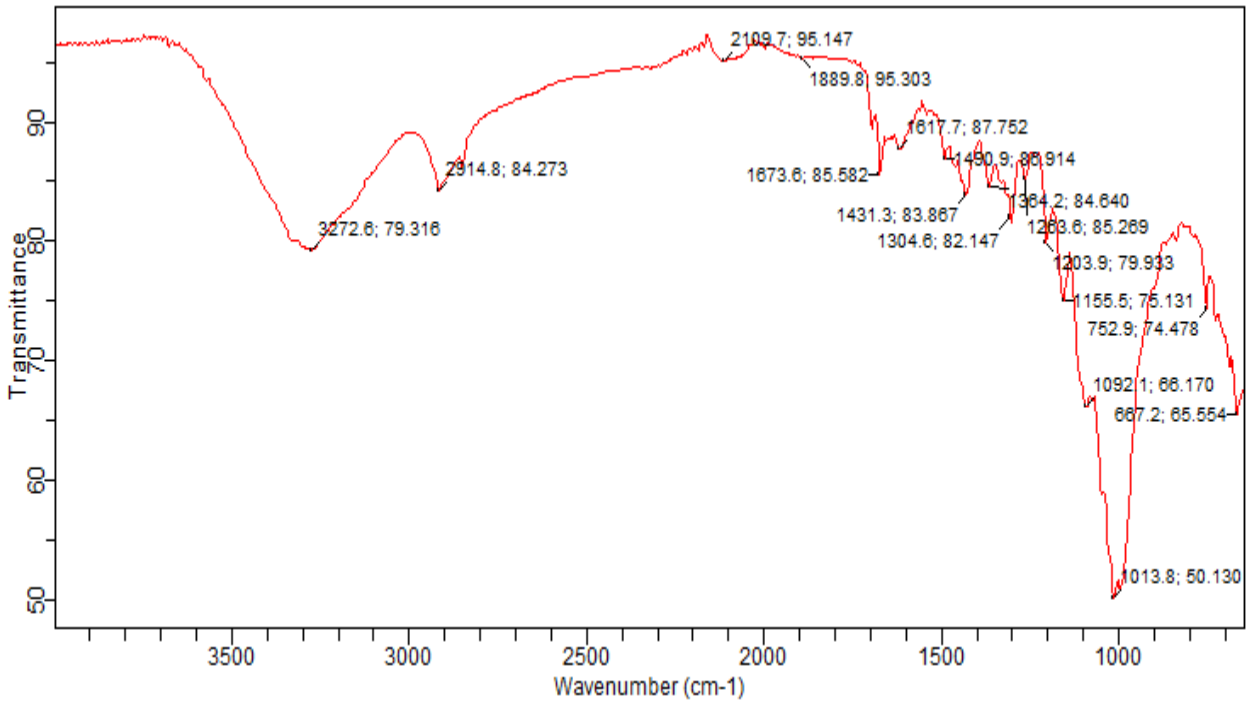

Figure 6: FTIR for batch D.

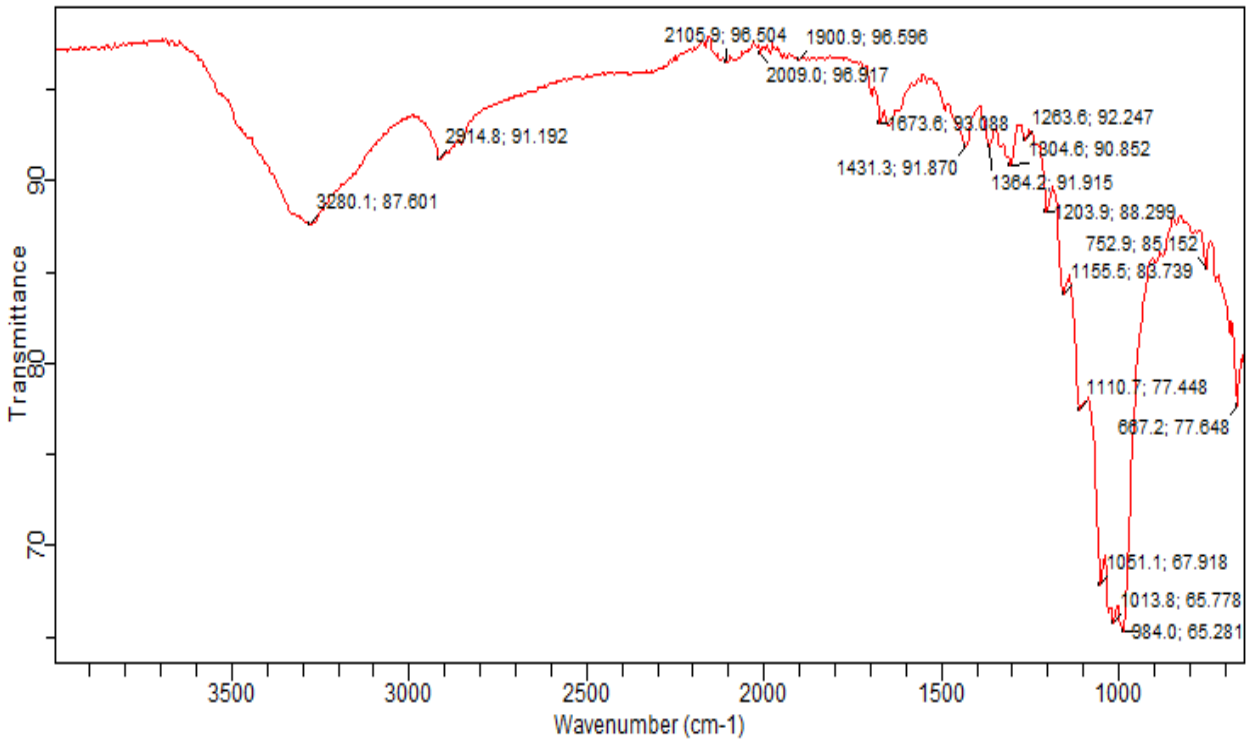

Figure 7: FTIR for batch E.

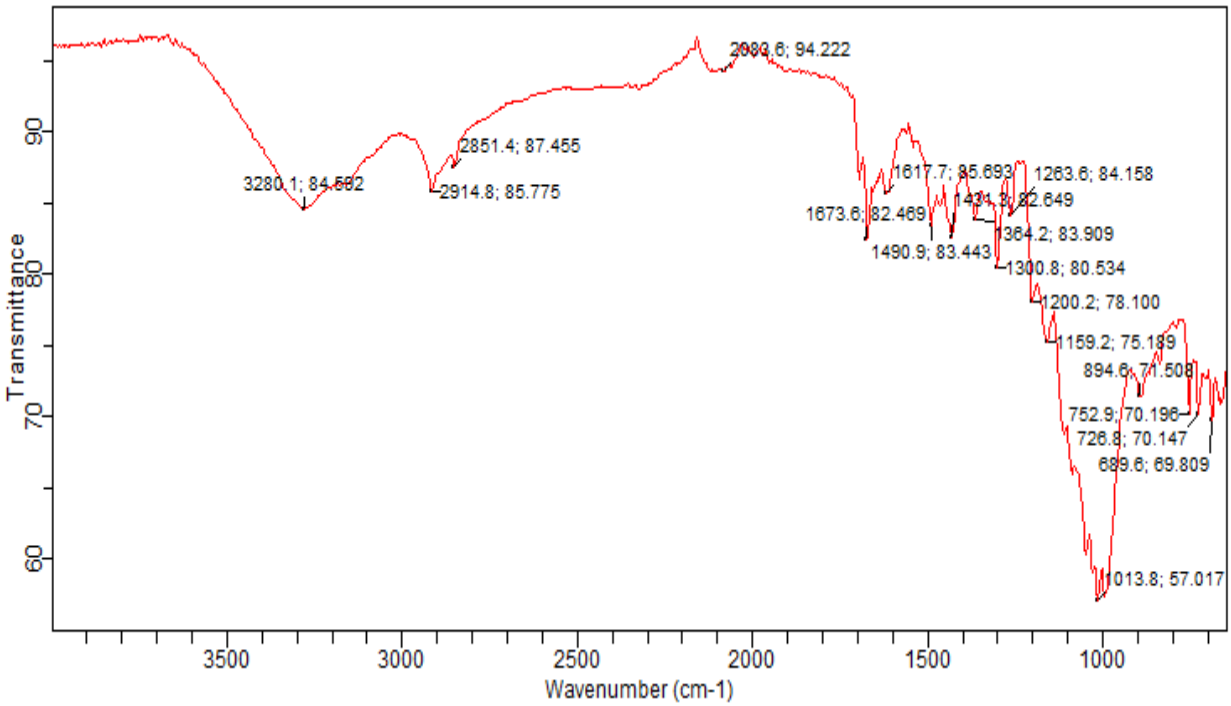

Figure 8: FTIR for batch F.

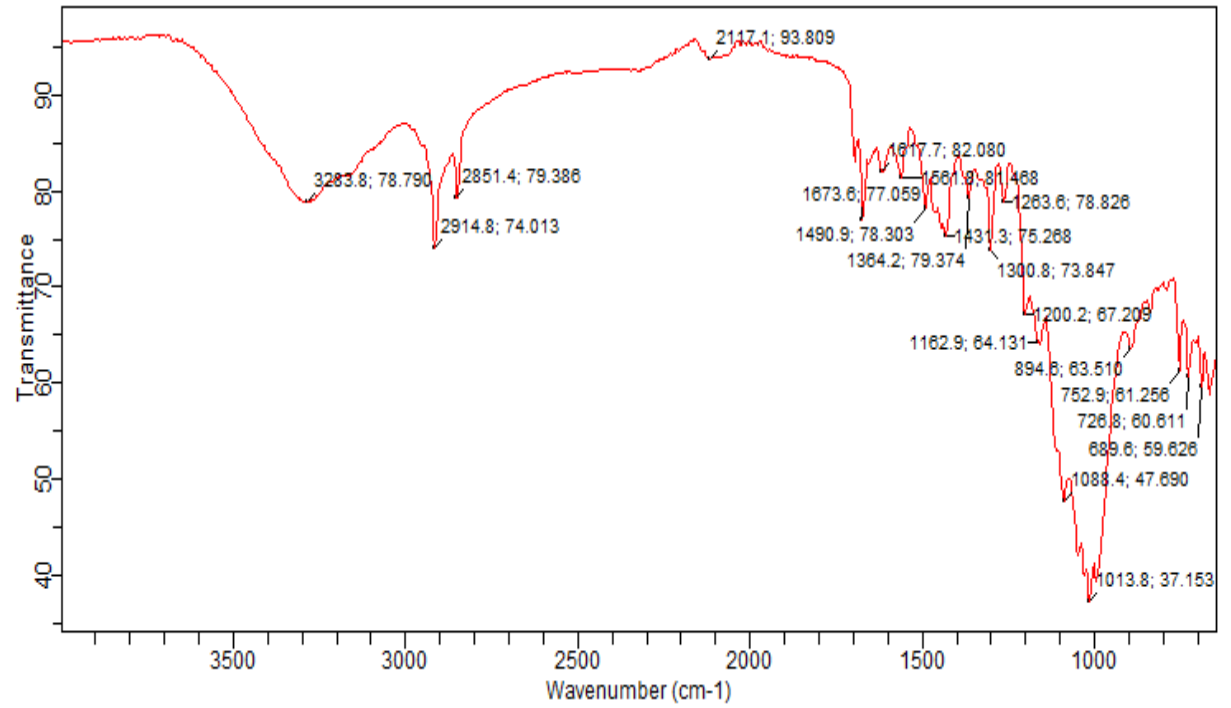

Figure 9: FTIR for batch G.

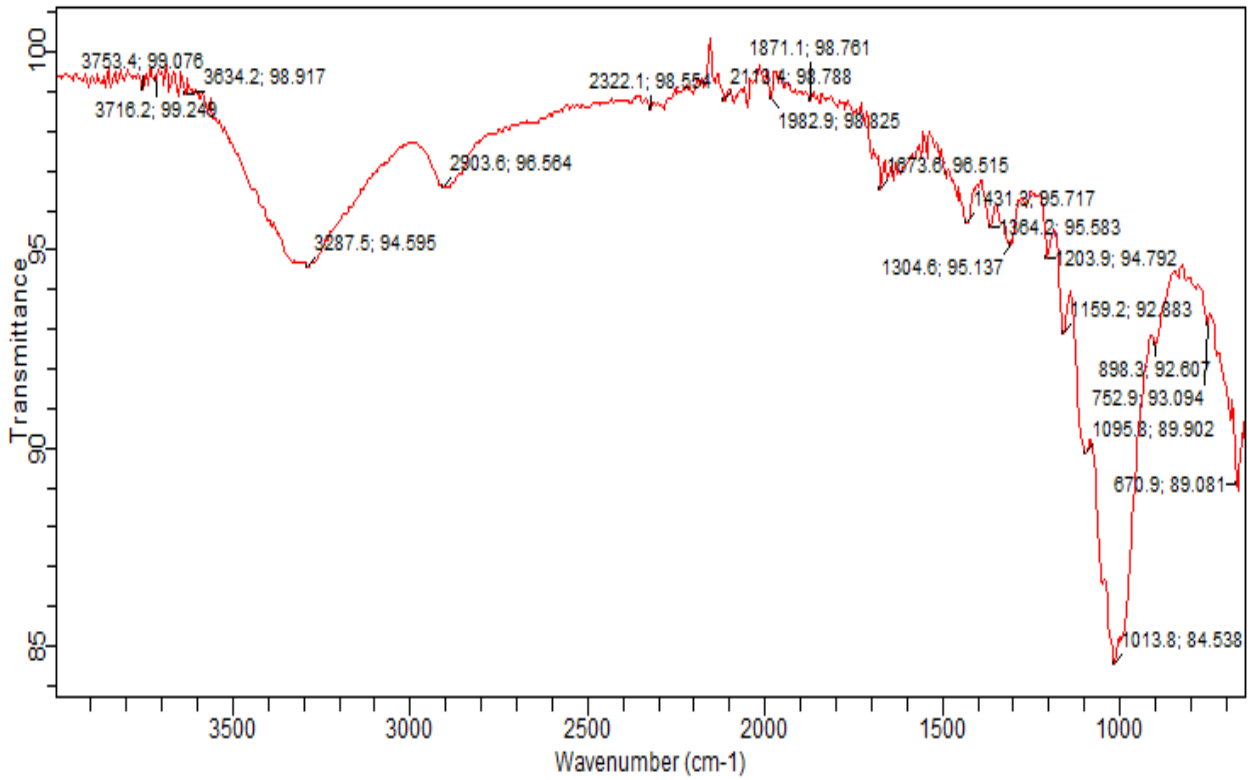

Figure 10: FTIR for batch H.

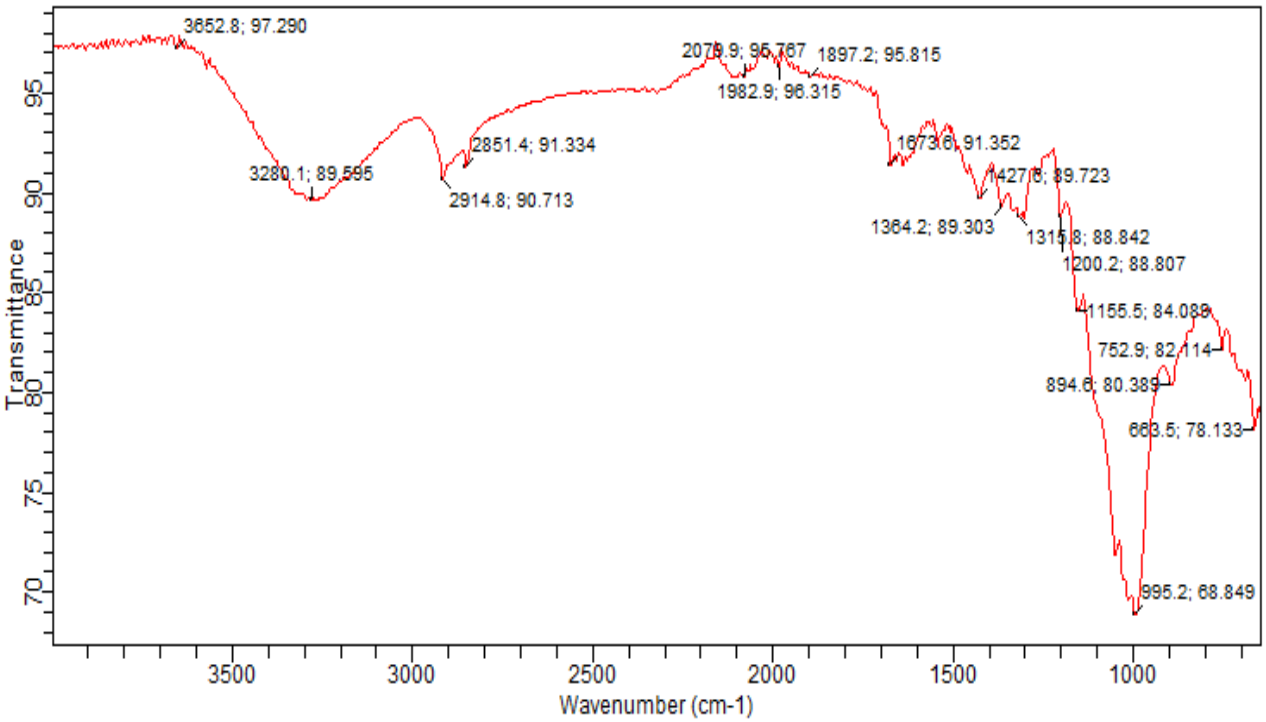

Figure 11: FTIR for batch I.

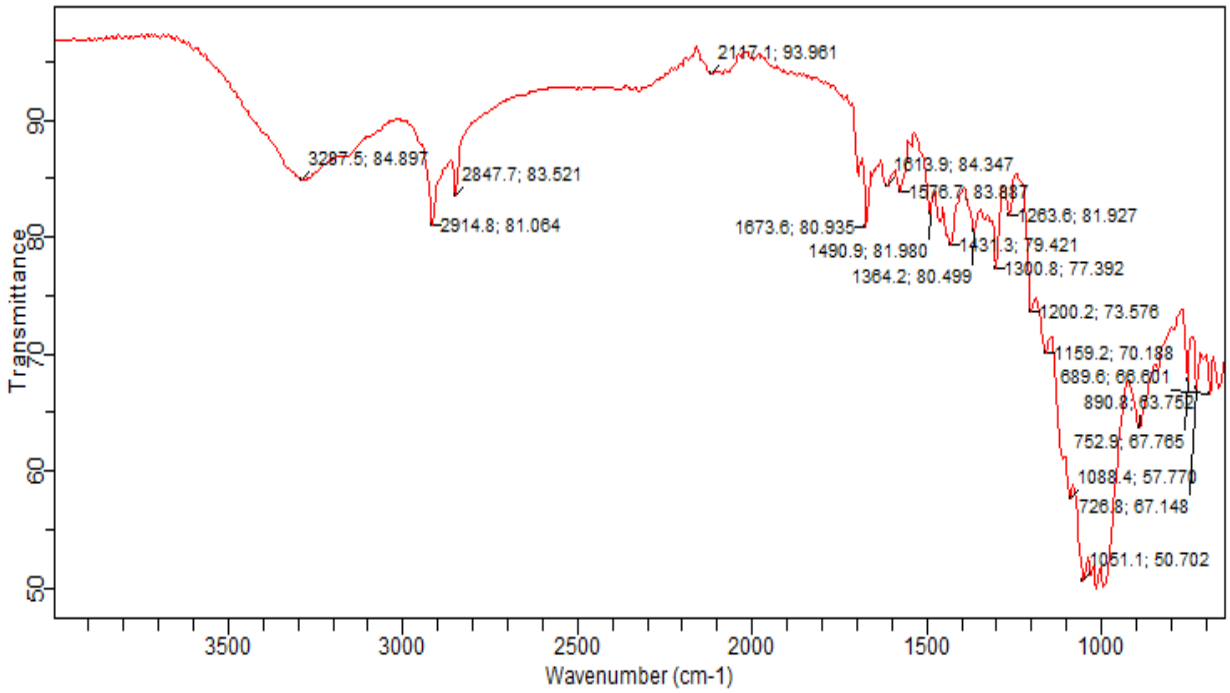

Figure 12: FTIR for batch J.

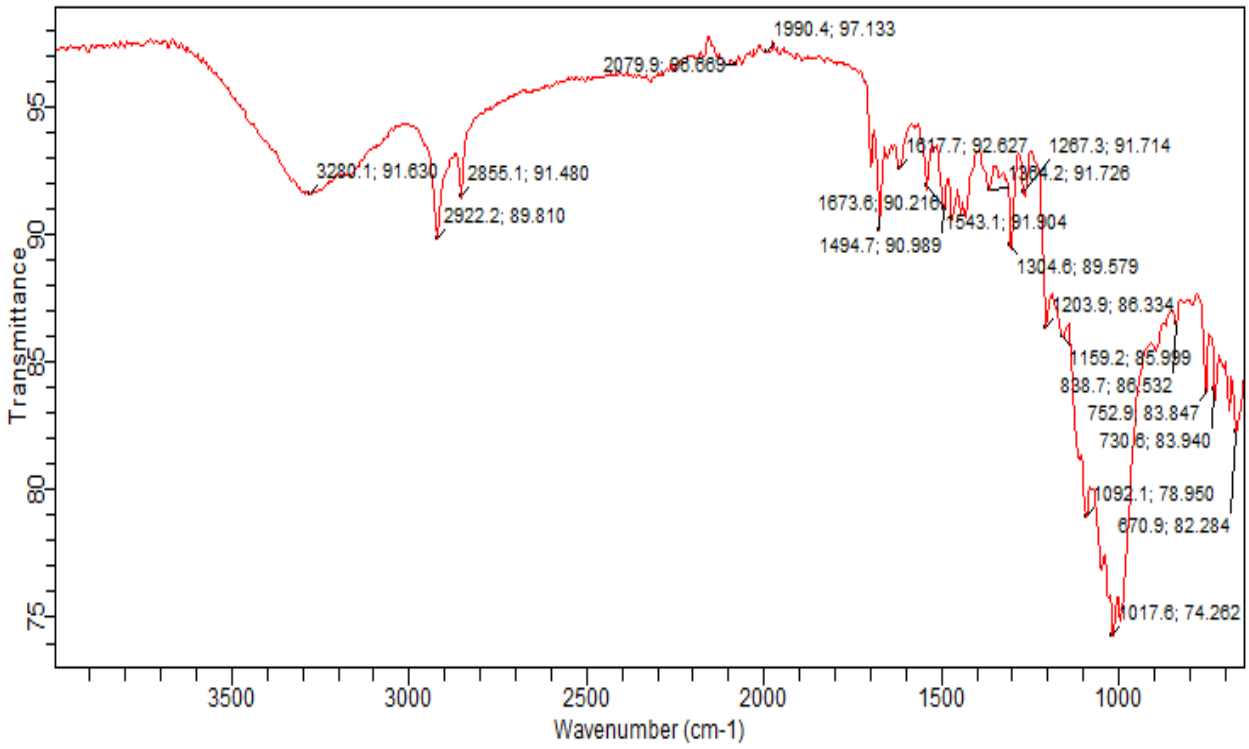

Figure 13: FTIR for batch Pure sample (PS).

Figures 3 – 13 shows the FTIR of Amlodipine besylate tablets, batches A – j, and the FTIR of the pure sample of the study drug sample.

Fourier Transmission Infrared Spectroscopy (FTIR) of the Amlodipine besylate tablets brands showed broad bands at ranges of 3272.0 cm^{-1} – 3852.8 cm^{-1} (at transmittance range of 72.0 – 99.5) which is relative to the C-H group of monochlorobenzene and it stretches between 3200 cm^{-1} -and 3000 cm^{-1}. Hence, broad bands at ranges of 3272.0 cm^{-1} – 3852.8 cm^{-1} respectively, were displayed by Amlodipine besylate brands which reportedly has proven to correspond to the C-H group of monochlorobenzene.

Results of the various dissolution gradients of ten brands of Amlodipine besylate tablets

Table 8 shows the dissolution profile of ten brands of Amlodipine besylate tablets.

Table 8: Dissolution profile of ten brands of Amlodipine besylate tablets.

TIME (min)	A	B	C	D	E	F	G	H	I	J
2	91.24	89.04	91.06	85.12	60.53	95.36	56.15	42.48	89.13	94.44
5	98.45	92.69	93.62	91.63	68.42	98.45	70.05	55.31	96.74	119.70
10	100.52	93.61	90.68	93.49	73.25	98.97	83.96	80.97	98.37	103.03
15	99.49	91.78	91.91	90.23	75.00	100.52	93.58	84.96	99.46	98.99
20	102.06	90.41	92.34	91.63	78.51	101.55	95.19	85.84	99.46	99.50
25	115.46	91.78	92.34	92.56	82.89	97.42	110.16	88.50	97.83	101.52
30	94.33	101.83	83.83	91.63	84.21	112.37	102.14	88.05	109.24	103.03
40	97.42	91.78	89.79	91.16	87.28	99.49	99.47	87.61	97.28	98.49
50	100.00	89.95	89.79	94.88	87.72	107.22	99.47	92.04	98.37	98.49
60	100.00	100.00	99.99	100.00	100.00	100.00	100.00	100.00	100.00	100.00

Results of the drug release study of Amlodipine besylate tablets

Figure 14 shows the drug release study of ten different brands of Amlodipine besylate tablets.

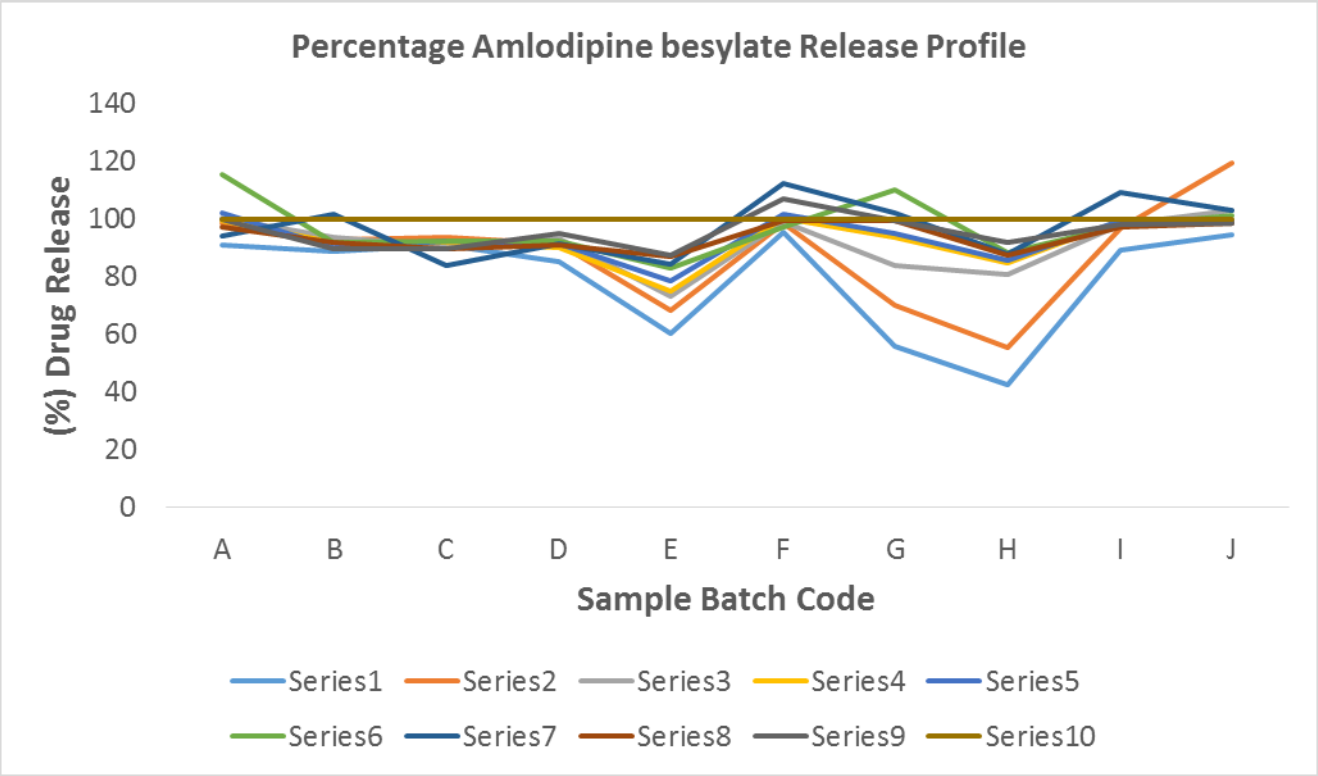

Figure 14: Drug release study of ten different brands of Amlodipine besylate tablets.

Table 8 shows the dissolution profile of ten brands of Amlodipine besylate tablets.

Dissolution test is an important *In-vitro* qualitative and quantitative tool, which can provide important information about bioavailability of a drug as well as batch-to-batch consistency. The ultimate aim of performing dissolution tests is to predict the extent of release and absorption of the administered drug *in-vivo*, (*in-vivo-in-vitro* correlation).[20] The dissolution test described in USP 39 for Amlodipine tablets indicates that not less than 80% of the labelled amount of API should be dissolved in 30 minutes (United States Pharmacopeia (USP), 2016). Thus, the ten samples complied in terms of drug release rate. The dissolution profiles shown in Figure 14 indicate that most of the sample batches passed the test. Products had no much differences in dissolution performance.[21]

CONCLUSION

Despite the presence of substandard performance in isolated parameters (e.g., friability in one brand), the majority of the evaluated generic amlodipine brands marketed in Port Harcourt, Nigeria demonstrated acceptable physicochemical properties, content uniformity, and *in-vitro* dissolution behaviour comparable to the innovator product. These findings support the cost-effective use of quality generic alternatives in hypertension management in Nigeria, while emphasizing the need for ongoing post-market

surveillance to detect and exclude substandard or falsified products that could compromise therapeutic outcomes and public confidence in generics.

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