



Research Article

Quality Assessment of Some Selected Brands of Amoxicillin Capsules in Drug Market, Kano - Nigeria

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ARTICLE INFO: ABSTRACT

Keywords:

Amoxicillin,
Quality,
Uv-
Spectrophotometry,

Amoxicillin is a semi-synthetic, b-lactam antibiotic used to treat bacterial infections caused by susceptible micro-organisms. It is usually prepared in different dosage forms, which include tablet, capsule, powder for oral suspension and parenteral. The World Health Organization (WHO) has promoted using generic brands to make medicines affordable. Generic substitution could be considered when a generic copy of a reference drug contains identical amounts of the same active ingredient in the same dose formulation and route of administration. The study evaluated and compared some of the quality parameters of different generic brands of Amoxicillin capsules marketed in Kano State, Nigeria. Physical appearance test, Uniformity of weight test, Identification test and Assay of five (5) samples of Amoxicillin capsules were conducted using Standard methods (B.P. 2009) and (USP, 32). The result of the physical appearance test indicated that four (4) samples (JY01, JY02, JY03 and JY04) passed the test with an off-white appearance except for sample JY05, which failed specifications with a white colour. The same four samples passed texture specification, but JY05 failed by appearing as fine powder against crystalline powder. Likewise, identification for JY01, JY02, JY03 and JY04 showed a positive colour of dark yellow solution, while JY05 showed dark green, indicating a failed result. Similarly, the uniformity of weight of all samples, 13.52 g, 13.38 g, 13.24 g, 13.28 g and 8.41 g for JY01 - JY05, respectively, JY05 still failed this important test. Assay results of samples JY01 - JY04 passed the test with 126.4 %, 127.0 %, 128.0 %, and 129.0 %. Sample JY05 deviated from the specifications with a negative value of 0.46 %. Therefore, all the samples, except JY05, can be used interchangeably without recourse to their brand names.

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INTRODUCTION

Amoxicillin is an acid, a stable and semi-synthetic drug that belongs to a class of antibiotics called Penicillin's (Beta-lactam antibiotics). It is effective against many Gram-positive and Gram-negative bacteria in humans and animals. Amoxicillin, a beta-lactam antibiotic, is among the most widely prescribed antibiotics for various conditions and patient groups (Salvo *et al.*, 2007).

Post-market surveillance or monitoring involves all activities undertaken to obtain more data and information about a product after it has been granted marketing authorization and made available for public use. Regulatory agencies rely on limited information obtained during clinical trials and, to some extent, scientific literature as guides to granting marketing of medicines for public use. Therefore, it is imperative to conduct post-market surveillance or monitoring of approved medicines to adequately assess the quality, therapeutic effectiveness and safety of medicines for the larger public. Quality control is part of Good manufacturing practice (GMP) that is concerned with sampling, specifications, testing, documentation and release procedures, which ensure that the necessary and relevant tests are carried out and that the materials are not released for use, not products released for sale or supply until their quality has been judged to be satisfactory. (WHO, 1994). The safety and efficacy of a pharmaceutical dosage form can be guaranteed when its quality is reliable. The efficacy of pharmaceutical dosage forms depends on their formulation properties and manufacturing methods. Hence, the quality of dosage forms will likely vary. (Odeniyi, *et al.*, 2003).

The increase in the number of generic drug products from multiple sources has placed people and prescribers in a position to select one from among several seemingly equivalent products. (El Attug M, *et al.* 2015). Many of these products are inexpensive and affordable, but there are uncertainties about their quality (Nwodo *et al.*, 2007). Several studies showed that switching from branded to generic medicine might result in pharmacokinetics/pharmacodynamics profile changes, leading to sub-therapeutic

concentration or therapeutic failure and/or adverse reactions. (Moawia, *et al.*, 2017) It is essential to do bioequivalence studies for generic products because of any significant difference in the rate and extent by which the therapeutic ingredients become available at the site of drug action, administered under uniform conditions in an adequately designed study. (Shargel *et al.*, 2016)

Variable clinical responses to drugs presented as generics and batch-to-batch inconsistencies have been reported; such unacceptable trends were exhibited in some drug products, including Amoxicillin. Quality control procedures, which are valuable tools for batch-to-batch consistency in manufacturing and should be performed for every drug product, require analysis for their biopharmaceutical and chemical equivalency. These methods ensure that any of the generic products can be used interchangeably. The observation is that most generics have much lower shelf prices than the innovator products, raising the likelihood of unequal product performance unless they differ significantly in properties regarding safety and/ or efficacy (Ngwuluka *et al.*, 2009).

Post-market surveillance or monitoring involves all activities undertaken to obtain more data and information about a product after it has been granted marketing authorization and made available for public use. Therefore, it is imperative to conduct post-market surveillance or monitoring of approved medicines to adequately assess the quality, therapeutic effectiveness and safety of medicines for the larger public. The increase in the number of generic drug products from multiple sources has placed people and prescribers in a position of selecting one from among several seemingly equivalent products (El Attug M *et al.*, 2015). Many of these products are inexpensive and affordable, but their quality is uncertain (Nwodo *et al.*, 2007). Therefore, there is a need for quality assessment of this Pharmaceutical product, the Amoxicillin capsule.

MATERIALS AND METHODS

Some Reagents and Chemical used

Distilled water

Methanol

Sulphuric acid-formaldehyde

Sulphanilic acid

Sodium nitrite

Hydrochloric acid

Equipment used are:

Analytical weighing balance (Ohaus Corp. Pine Brook, NJ, USA AR223CN)

Dissolution test apparatus

Ultraviolet (UV) spectrophotometer (JENWAY 7315, Designed and Manufactured in the UK by Bibby Scientific Ltd)

Water-bath

Ultrasonic device (BRANSONIC ULTRASONIC CLEANER 5510E DTH EDP: CPN 952:538, Product of the United States, Assembled in Mexico)

METHODS

Sampling Area

Sabon-gari Market, Kano State, Nigeria.

Sample Collection

Five (5) different brands of Amoxicillin capsules were randomly purchased at different retail or wholesale pharmacy shops and drug outlets in Sabon-gari market, Kano State, Nigeria, in December 2021 and coded as JY01, JY02, JY03, JY04 and JY05 which were stored at room temperature. All the capsule samples were labelled to contain 500 mg of Amoxicillin as the Active Pharmaceutical Ingredient in their pack. The sample's Name, Manufacturer, Production and Expiry dates, NAFDAC registration number and Batch number were recorded as shown in Table 1 below.

Table1: Amoxicillin Capsules (500mg) brands randomly selected from the Market

Brand	Country of origin	Batch No	NAFDAC No	Mfg Date	Expiry Date
JY01	India	1721-314	C4-0680	July, 2021	June, 2024
JY02	China	220310	04-5399	March,2022	March, 2025
JY03	Nigeria	1020022	A4-9819	Nov, 2022	Oct, 2025
JY04	Nigeria	220552	B4-9797	May, 2022	May, 2025
JY05	India	H026051	04-4310	Feb,2022	Jan, 2025

Identification Test for Amoxicillin Capsules

Physical Appearance Test

A sachet/blister containing 10 capsules for each sample was randomly selected from the pack, and the blisters were broken to expose the capsules. The capsules were opened, and each sample's powder was examined for colour, texture and taste according to the B.P 2009 official method.

Chemical Identification Test

A quantity of Amoxicillin powder, measuring 2 mg, was placed in a test tube 150 mm long, followed by 0.05 ml of distil to moisten the powder. Then 2 ml Sulphuric acid-formaldehyde reagent was added. The contents of the test tube were mixed thoroughly by swirling the test - tube and then placed in a water bath for 1 minute (B.P, 2009). This test was conducted for each brand sample and the Standard sample.

Uniformity of Weight Test

Twenty (20) units of capsules from each brand were packed and weighed. The capsules were

opened, the contents were emptied as completely as possible, and the empty shells were weighed. The net difference was determined by subtracting the weight of the shells from the weight of the intact capsules. The average weight of the capsules for each brand sample and the percentage deviation from the mean value were then calculated (U.S.P-NF, 2017).

Assay Test

Solutions Preparation

The chemicals were of analytical grade, and the solutions were freshly prepared. The following working solutions were prepared.

Amoxicillin solution (100 microgram/ml)

Sulphanilic acid (0.5% w/v)

Sodium Nitrite (0.2% w/v)

Hydrochloric Acid (0.01 N)

Sodium Carbonate solution (0.5 N)

Spectrophotometric Determination of Amoxicillin

The method used for the Assay was adopted from Hemn *et al.* (2015).

In a series of 25 mL volumetric flasks, each flask containing 0.5 mL HCl (0.01 N), 1.0 mL NaNO₂ (0.2 %) and 1.0 mL of Sulphanilic acid (0.5 %) to produce a water-soluble, colourless diazonium ion. The formed diazonium ion was coupled with 7.5 – 75 µg of Amoxicillin to form an orange azo compound after adding 1.0 mL of

Na₂CO₃ (0.5 N). The volume in each flask was made to the mark with distilled water, and the coloured product was monitored spectrophotometrically against a reagent blank at 455 nm. The reagent blank was prepared in the same manner but without Amoxicillin.

RESULTS

Physical Appearance Test Result

Table 2 below showed the results of Physical appearance test which indicated the colour exhibited by each sample brand.

Table 2: Result of Physical Appearance Test

Samples	Color	Taste	Texture
JY01	Off-white	Less bitter	Crystalline powder
JY02	Off-white	Less bitter	Crystalline powder
JY03	Off-white	Less bitter	Crystalline powder
JY04	Off-white	Less bitter	Crystalline powder
JY05	White	Very bitter	Fine powder

Uniformity of Weight Test Result

Below is a table that showed how the weight of each brand sample was measured and the weight difference was calculated.

Table 3: Uniformity of Weight Test Result

Samples	Weight of intact capsule (g)	Weight of shells (g)	Net difference (g)
JY01	13.523	1.861	11.662
JY02	13.382	2.005	11.377
JY03	13.236	1.866	11.370
JY04	13.284	2.189	11.095
JY05	8.412	2.040	6.372

Table 4 shows the chemical identification results for the standard and all five (5) brand samples.

Table 4: Chemical Identification Test Result of all brands

Samples	Result
JY01	Dark yellow solution in color
JY02	Darker yellow solution in color
JY03	Dark yellow solution in color
JY04	Darker yellow solution in color
JY05	Dark army green in color

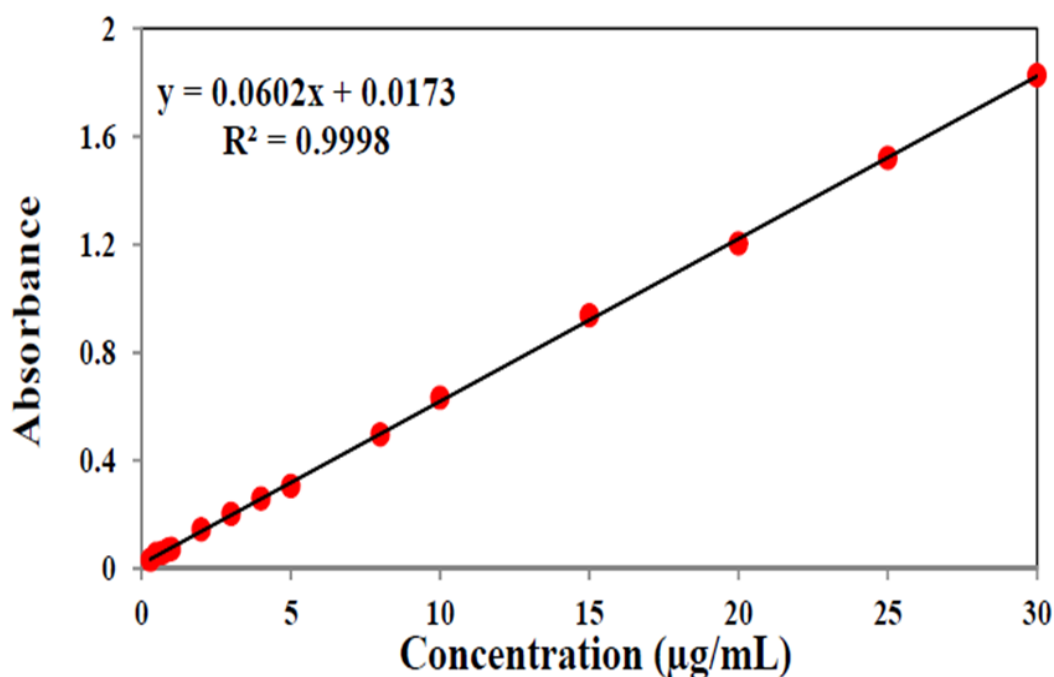
To calculate the Assay of all the brands, the Absorbance for each solutions of sample brands was recorded as shown in table 5.

Table 5: Absorbance Readings for the brand samples

Samples	Wavelength (nm)	Time & Date	Transmittance (%)	Absorbance
JY01	455 nm	5/10/2023 2:36pm	0.015	3.821
JY02	455 nm	5/10/2023 2:37pm	0.014	3.842
JY03	455 nm	5/10/2023 2:38pm	0.013	3.872
JY04	455 nm	5/10/2023 2:39pm	0.013	3.900
JY05	455 nm	5/10/2023 2:40pm	107.568	-0.032

Calibration Graph

A calibration curve was constructed under the chosen optimum conditions (Figure below 1). The graph showed that the result colour system obeyed Beer's law in the concentration range of 7.5 –750 µg of Amoxicillin in a 25 mL of final volume (i.e. 0.3 – 30 µg/mL of Amoxicillin), which showed Linearity.

**Fig 1:** Calibration curve under chosen optimum conditions

From the observed absorbance of each brand sample, the corresponding Amoxicillin concentration was calculated using the equation obtained from the calibration curve. Hence, the percentage of Amoxicillin was also calculated, as shown in Table 6 below.

Table 6: Assay Result of each brand Sample

Samples	Concentration (mg)	Percentage (%)
JY01	631.8	126.36
JY02	653.2	127.04
JY03	640.2	128.04
JY04	644.8	128.96
JY05	- 2.3	- 0.46

DISCUSSION

The samples of Amoxicillin capsules examined were registered with NAFDAC and have a reasonable shelf life, as shown in Table 1. This indicates that the drug products met NAFDAC requirements for Pharmaceutical Products in Nigeria. Similarly, all the samples have impressive appearances, even though there was variation in the organoleptic properties of the samples, as shown in Table 3. The increase in the number of generic drug products from multiple sources has placed people and prescribers in a position to select one from among several seemingly equivalent products. (El Attug, *et al.* 2015).

Likewise, four (4) of the brand's samples complied with the physical appearances test such as colour, taste and texture according to the BP (2009) to have an off-white, less bitter and free-flowing. Sample JY05 failed this test, primarily suggesting a poor quality drug and, hence, less pharmacological effect.

Samples examined have a significant weight of powder and weight of shells except for sample JY05. Thus, there is weight uniformity for samples JY01 - JY04, except sample JY05. This indicates Good Manufacturing Practice (GMP) for JY01 - JY04 Samples (USP-NF-2017b). Uniformity of weight serves as an indicator of the consistency of active pharmaceutical ingredients in solid dosage units. Weight uniformity test is consequently an important parameter to confirm that the drug content in each drug unit is distributed within a narrow range around the label claim. In oral dosage forms, any weight deviation reflects a variation in the content of the active pharmaceutical ingredient (USP-NF-2017).

JY01 and JY03 showed a dark yellow colour solution as stated in the identification test of BP (2009); Samples JY02 and JY04 had a Darker yellow colour of solution, which is slightly

different from the BP (2009) Specifications. This might be due to some effects of interferences or impurities by the excipients. At the same time, JY05 deviated from the specifications, possibly due to the adulteration of the powder or the absence of API in the formulation. This implied that the product was Fake based on the findings. Therefore, there would not be any therapeutic value associated with the fake product.

From BP (2009), the acceptable Assay value for an Amoxicillin capsule is 95.0 % - 102.0 %, and the acceptable criteria for Amoxicillin capsules in USP (32) is 90 % - 120 %. The samples studied are within this range, except JY05, which showed a more significant value by more than 5% deviation. Distinct variations mean ineffective therapeutic drug levels or overdosing, which results in toxicity (USP-NF-2017). This is similar to a study by Moawia *et al.* (2017) on amoxicillin tablets, where all tested tablets for Amoxicillin content deviated by less than 5%.

The concern about the quality of drugs sold increases yearly, not only in commercial terms but also in legal and ethical aspects, since patients' health

depends on the quality and effectiveness of drugs. (AQuresh, S, 2016).

JY05 sample can be considered substandard medicine that can increase mortality and morbidity due to harmful side effects or allergies or endangered drug-resistant pathogens that limit the therapeutic effectiveness of legitimate medicines (Newton *et al.*, 2006).

CONCLUSION

The samples of Amoxicillin Capsules coded JY01 - JY05 collected from the Kano drug market showed the presence of Amoxicillin powder and have an acceptable level of Pharmaceutical Standard and can be used for the intended use as well as administered

interchangeably with the exception of sample JY05 that consistently failed the tested quality parameters.

RECOMMENDATIONS

1. This study should be carried out regularly, especially when new drug brands are on the market.
2. Further studies should be carried out on Bioequivalence studies of some selected brands of Amoxicillin Capsules.
3. Post-marketing surveillance of pharmaceuticals by regulatory bodies should be encouraged to ensure the quality of drugs through different distribution channels.
4. More advanced techniques should be employed to carry out pharmaceutical equivalence studies.

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