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Comparative Study of the Physical Characteristics of Some Commercially Available Brands of Amoxicillin Capsules

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Authors' contributions

All authors were involved in the literature searches. Author AJO designed the research topic, the procedure and involved in the experimental work. Author OPO performed the statistical analysis, and was involved in the write up. Author FA was actively involved in the experimental work and wrote the first draft of the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To assess the quality of 10 brands of Amoxicillin Trihydrate 500 mg capsules.
Study Design: Experimental.
Place and Duration of Study: Experimental drugs were purchased from pharmacy in Okada and Benin and experimental work was carried out in Pharmaceutical Technology laboratory, Igbinedion University Okada
Methodology: A specific quality control method was developed for the determination and comparative study of the capsules and the quality was assessed through evaluation of organoleptic properties, uniformity of weight, disintegration, dissolution using the spectrophotometric method, moisture uptake as well as comparing analytical method (titration) and HPLC method for the determination of content uniformity. All the brands have suitable appearance.
Results: 7 brands passed the weight variation test, 9 brands passed the content uniformity test with

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HPLC method being faster and accurate, all the brands passed the disintegration test, 6 brands passed the dissolution test and for moisture uptake, 2 brands had a rapid increase in weight.
Conclusion: From the results obtained, it can be said that the majority of the commercially available brands of amoxicillin trihydrate are up to pharmaceutical standard of quality and are safe for use by consumers.

Keywords: Amoxicillin trihydrate; uniformity; weight variation; content uniformity; disintegration; dissolution; stability; absorption; encapsulation.

ABBREVIATIONS

WHO: World Health Organization; BP: British Pharmacopoeia; PCN: Pharmaceutical Council of Nigeria; EPI: Emzor Pharmaceutical Industries; HPLC: High-performance liquid Chromatography; USP: United States Pharmacopeia; EP: European Pharmacopeia.

1. INTRODUCTION

Capsule is the most versatile of all dosage forms. Capsules are solid dosage forms in which one or more medicinal and inert ingredients are enclosed in a small shell or container usually made of gelatin [1]. They are available in various shapes and sizes to provide dosing flexibility, and contain a single dose of one or more active ingredients. They are intended for oral administration, but preparations for alternative applications, such as vaginal or rectal, are also available in this presentation [2]. These preparations may require a special formulation.

Capsule shells and contents may contain excipients such as diluents, solvents, surface-active substances, opaque fillers, antimicrobial agents, sweeteners, coloring matter, flavoring substances, disintegrating agents, lubricants, and substances capable of modifying the behaviour of the active ingredient in the gastrointestinal tract [3]. The contents should not cause deterioration of the shell. When excipients are used, it is necessary to ensure that they do not adversely affect the stability, dissolution rate, bioavailability, safety, or efficacy of the active ingredient(s); there must be no incompatibility between any of the components of the dosage form [4].

The powder also must have a certain degree of subtlety. When capsule is a very fine particle size, then the capsule was more homogenous, so that the faster dissolution of drugs in blood levels rapidly achieved with high surface area will give a large adsorption capacity. This is important for capsule antacids, anti-diarrhea and antidote [5].

1.1 Amoxicillin Capsule

Formulation of Amoxicillin Capsules, USP contains amoxicillin, a semisynthetic antibiotic, an analog of ampicillin, with a broad spectrum of bactericidal activity against many Gram-positive and Gram-negative microorganisms [6]. Chemically, it is (2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p - hydroxyphenyl) acetamido] - 3,3 - dimethyl - 7 - oxo - 4 - thia - 1 – azabicyclo [3.2.0] heptane - 2 - carboxylic acid trihydrate. The properties of this capsule is shown in Table 1.

Amoxicillin formerly amoxycillin is a moderate-spectrum, bacteriolytic, β-lactam antibiotic used to treat bacterial infections caused by susceptible microorganisms. It is usually the drug of choice within the class because it is better absorbed, following oral administration, than other β-lactam antibiotics. Amoxicillin is one of the most common antibiotics prescribed for children. The drug became available in 1972 [7,8]. Amoxicillin is susceptible to degradation by β-lactamase-producing bacteria, which are resistant to a broad spectrum of β-lactam antibiotics, such as penicillin. For this reason, it is often combined with clavulanic acid, a β-lactamase inhibitor. This increases effectiveness by reducing its susceptibility to β-lactamase resistance.

Amoxicillin was one of several semi-synthetic derivatives of 6-aminopenicillanic acid (6-APA) developed at Beecham in the 1960s. It became available in 1972, and was the second aminopenicillin to reach the market (after ampicillin in 1961) [9,10]. Co-amoxiclav became available in 1981 [11].

This drug acts by inhibiting the synthesis of bacterial cell walls. It inhibits cross-linkage between the linear peptidoglycan polymer chains

that make up a major component of the cell walls of both Gram-positive and Gram-negative bacteria [12]. It has two ionizable groups in the physiological range (the amino group in alpha-position to the amide carbonyl group and the carboxyl group) [13].

Streptococcus, Bacillus subtilis, Enterococcus, Haemophilus, Helicobacter and *Moraxella* spp are generally susceptible to amoxicillin, while Citrobacter, Klebsiella and *Pseudomonas aeruginosa* are resistant to amoxicillin [14]. Some *E. coli* and most clinical isolates of *Staphylococcus aureus* have developed resistance to amoxicillin to varying degrees.

The shelf life of Amoxicillin 500 g is ten years. It is an antibiotic that is used to treat infections that are caused by organisms susceptible to amoxicillin effects [15]. People who are allergic to amoxicillin should not use it but try the penicillin antibiotics like ampicillin [16].

1.2 Aims and Objectives

To compare the physical characteristic of some commercially available brands of Amoxicillin capsules 500 mg using the weight variation, content uniformity, disintegration, dissolution and the stability of the drug using moisture uptake. This is done to evaluate the bioequivalence of the different brands which serves as a platform to access the quality and biological performance of the products upon administration.

2. METHODOLOGY

10 Different brands of Amoxicillin Trihydrate Capsules 500 mg each from different manufacturers were collected from various stores. The samples were properly checked for their manufacturing license number, batch number, manufacturing and expiry dates before purchasing. The reference standard was obtained from Emzor Pharmaceutical Industries Limited, Plot 3C Block A, Aswani Market Road, Isolo-Lagos, Nigeria. It has the following information; Batch Number: M524820, Manufactured Date: March 2013 and Expiry Date: February 2017.

10 commonly used capsule brands were obtained from pharmaceutical stores in Lagos, each capsule brand was labeled 500 mg by the manufacturers. The method recommended assaying the content uniformity by the British Pharmacopoeia (BP), 2011 [17] was titration method, reference standard method, dissolution and the disintegration methods. Standards of capsule properties are published in various international pharmacopoeias' (USP, EP, etc.). The various brands of amoxicillin capsules were evaluated using the following tests:

2.1 Assessment of Organoleptic Properties

The analyses of the capsules were carried out immediately after purchase. Preliminary examination of the organoleptic properties was carried out for all the samples collected. The following properties were evaluated for all the capsules: Color, inscription on the surface, taste, odor and description for all the samples and differences in observation were handled objectively.

2.2 Uniformity of Dosage Unit

Weight Uniformity: One capsule of Amoxicillin Trihydrate was weighed individually, taking care that the identity of the capsule is preserved (it was opened without losing any part of the shell and the contents removed as completely as possible). The weight of the shell was also weighed and shown in Table 5. The difference between the weighing gives the weight of the contents. The procedure was repeated with other 19 capsules with percentage deviation ± 7.5%.

2.3 Moisture Permeation Test (MOISTURE UPTAKE)

The degree and rate of moisture penetration is determined by packaging the dosage unit together with a colour revealing desiccant pellet. The test was carried out as follows;

1. 10 capsules of Amoxicillin Trihydrate were exposed to known relative humidity over a specific period of time (one week) with the exception of Saturday and Sunday. The results for disintegration time and moisture uptake were shown in Tables 6 and 7 respectively.
2. Observation and weight variation was taken for any colour change or increase in weight; for every 24 hours.

3. RESULTS

All the capsules have suitable appearances. They were encapsulated with unbroken inscription evenly coloured. Packaging of all the brands was also intact at the time of sampling.

Tables 3 and 4 show results for weight variation, AMX 2, AMX 6 and AMX 7 did not pass the weight variation test with 10 of AMX 6 capsules respectively differing from the average by more than the permitted limit. The BP and USP states that not more than 1 or 2 of the capsules should deviate from the average weight by more than the percentage deviation of ± 7.5 % for capsules with average weight more than 300mg and 10% for capsules with average weight less than 300 mg [18].

According to [19,20], amoxicillin capsule should release its active ingredient at 90-120% and 92.5-110% for the BP with label claim of 90-110%. The results for various tests carried out on the capsules were shown in Table 8. The titration and HPLC tests were normal, except for AMX 6 that has a low drug percentage assay. The failure could be due to weight variation. In the titration method, AMX 3 and AMX 5 showed a high assay but still falls within the range as stated in the British.

Pharmacopoeia: This could be as a result of high active ingredient in the weight. In the HPLC method for the first injection, AMX 4, AMX 7 and AMX 8 also showed a high assay as shown in Fig. 2.

3.1 Disintegration

Dissolution studies shown in Fig. 3 give an idea of the amount of drug available for absorption after oral administration. Drugs with poor dissolution profile will not be available in the body system or target organ/tissue to elicit therapeutic effect. The British Pharmacopoeia, 2011 [21] states that 80% of the capsule drug should dissolve within 60 minutes.6 brands passed the test while the remaining 4 (AMX 1, AMX 5, AMX 6, AMX 8) failed the dissolution test and hence, sufficient amount of the drug would not be available for absorption to elicit the expected therapeutic effect when administered.

The complexity of packaging materials and the highly technological nature of medicinal products are such that manufacturers are confronted with significant problems [22,23]. Interaction between packaging and such products is possible due to the combination of a multiplicity of container components and active pharmaceutical ingredients, excipients and solvents used in a variety of dosage forms [24]. This study shows a gradual increase in moisture uptake with AMX 2 and AMX 6 showing a rapid increase in moisture uptake with change in color indicating that it has absorbed moisture.

However, the link between the quality of a pharmaceutical product and the quality of its packaging, pharmaceutical packaging materials and systems must be subject, in principle, to the same quality assurance requirements as pharmaceutical products [25,26]. The appropriate system of quality assurance for the manufacture of pharmaceutical products should therefore follow the WHO guidelines for good manufacturing practices (GMP) [27]. The requirements to be met by pharmaceutical packaging and packaging materials as described in compendia.

4. DISCUSSION

The organoleptic parameters evaluated are shown in Table 2, all the capsules have suitable appearances. They were encapsulated with unbroken inscription evenly coloured. Packaging of all the brands was also intact at the time of sampling.

Tables 3 and 4 show the results for capsule weight and weight variation respectively, AMX 2, AMX 6 and AMX 7 did not pass the weight variation test with 10 of AMX 6 capsules respectively differing from the average by more than the permitted limit. Large variation in capsule weight may be due to not-free flowing granules during encapsulation or lubricants less or not mixed evenly [28] other reasons may be if the flow of granules is not good/not free flowing granules particle distribution is not normal, because the specific gravity is different, so that the flow is bad keep the uniform of particle size distribution. Not too many fines and not too many granules. A granule with large particle diameter which causes the resultant capsule has a variety of unsightly flow time. Large variation in capsule weight may be due to not-free flowing granules during encapsulation or lubricants less or not mixed evenly [29,30]. High variation in capsule weight will result in variation in the content of active ingredient in the capsule. Compliance to standard will help to ensure uniformity of dosage. Other capsule weight complied with the BP and USP weight variation standard which shows that all the recommended procedures were followed to ensure uniformity of the capsules. Weight variation generally is caused by high variation in capsule weight and this will result in variation in the content of active ingredient in the capsule.

Compliance to standard will help to ensure uniformity of dosage.

The result for the assay above shows the titration method and the HPLC method in which both passed the test except for AMX 6 that have a low drug percentage assay. The failure could be due to weight variation. In the titration method, AMX 3 and AMX 5 showed a high assay but still falls within the range as stated in the British Pharmacopoeia [31,32]. This could be as a result of high active ingredient in the weight. In the HPLC method for the first injection, AMX 4, AMX 7 and AMX 8 also showed a high assay. All the capsules passed the test with AMX 3 and AMX 4 having the fastest time of disintegration. AMX 6 has the slowest disintegration time. For a capsule to have a fast disintegration time, the excipients must have high wet ability [33,34] 6 brands passed the test while the remaining 4 (AMX 1, AMX 5, AMX 6, AMX 8) failed the dissolution test and hence, sufficient amount of the drug would not be available for absorption to elicit the expected therapeutic effect when administered. This study shows a gradual increase in moisture uptake with AMX 2 and AMX 6 showing a rapid increase in moisture uptake with change in color that indicates that it has absorbed moisture, the absorbance curve was shown in Fig. 1.

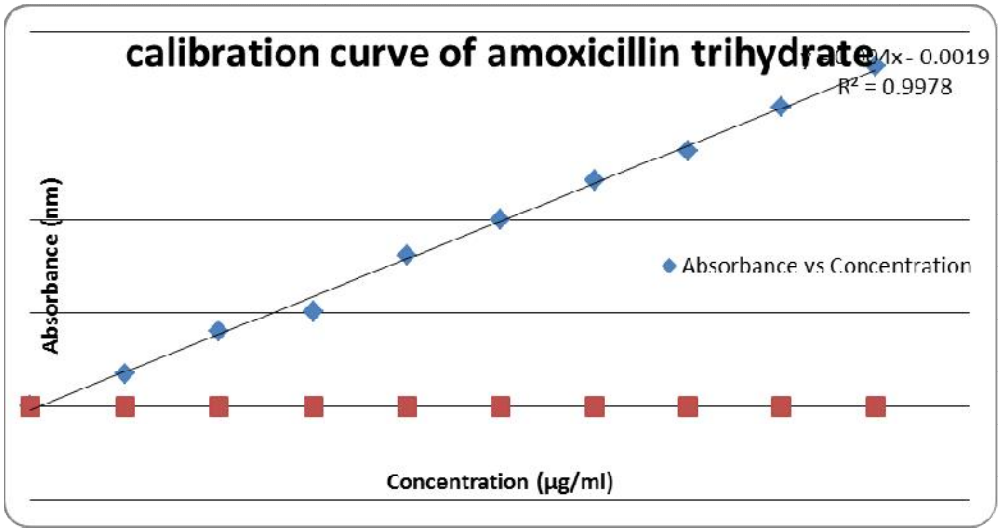

Fig. 1. Absorbance valves for calibration curve of Amoxicillin Trihydrate at I_{MAX} 272 nm

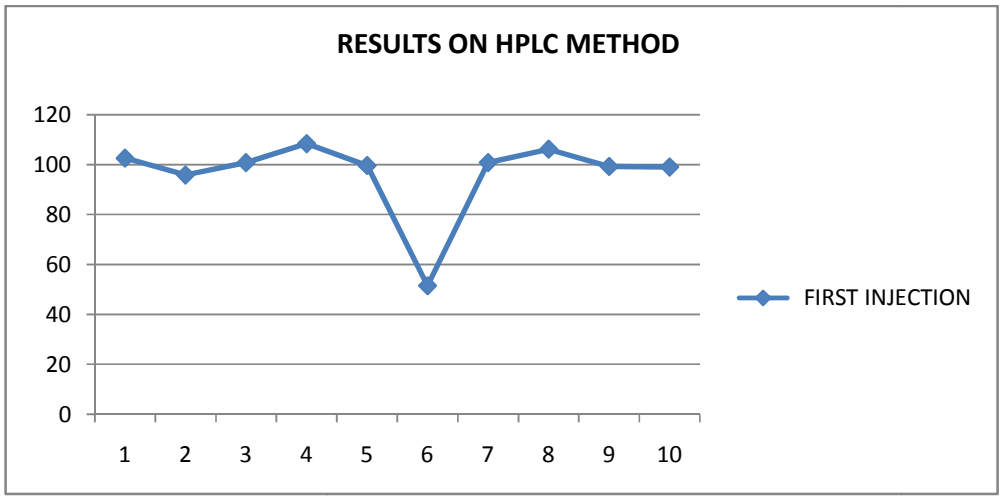

Fig. 2. Result of HPLC method

Table 1. Information on the various brands of amoxicillin trihydrate capsule 500 mg

Code no	Brand	Counry of origin	Nafdac no	Batch no	Name of Manufacturer	Manufactured date	Expiry date
AMX 1	Vitamox	Nigeria	04-2156	C20905	Strides vital nigeria limited	September 2012	August 2015
AMX 2	Nesmox	Nigeria	04-8623	NMC-041	Nostrum limited	May 2012	January 2014
AMX 3	Cimoxil	China	04-3888	121155	Cspc zhongnuo pharmaceutical co ltd	November 2012	November 2015
AMX 4	Emmox	Nigeria	04-5728	4729R	Emzor pharmaceutical industries limited	November 2012	November 2015
AMX 5	Imox	Nigeria	04-2284	060811	Chris-ejik pharmaceuticals and health care products ltd	August 2011	July 2013
AMX 6	Nemoxil	Nigeria	A4-4718	03 B	Nemel pharmaceutical industry limited	February 2013	February 2016
AMX 7	Lamox	Nigeria	04-4359	LAM.673	Ma cure industries limited	February 2013	January 2015
AMX 8	Floximox	Nigeria	A4-0701	2 005	Evans medical plc (rc1160)	April 2012	March 2015
AMX 9	Amoxil	India	04-2481	11 01 38	Medreich sterilab ltd	March 2011	March 2014
AMX 10	Moxitin	India	04-4800	101005	Clarison medicals limited	November 2012	November 2015

Table 2. The organoleptic parameters

Code no	Brand name	Colour	Taste	Odour	Description	Inscription
AMX 1	Vitamox	Scarlet & yellow opaque	Slightly bitter	Odorless	Crystalline powder	Amoxy 500 mg
AMX 2	Nesmox	Scarlet & yellow Opaque	Slightly bitter	Odorless	Crystalline powder	Nesmox 500 mg
AMX 3	Cimoxil	Scarlet & yellow opaque	Slightly bitter	Odorless	Crystalline powder	Cimoxil 500 mg
AMX 4	Emmox	Scarlet & yellow opaque	Slightly bitter	Odorless	Crystalline powder	Emzor 500 mg
AMX 5	Imox	Scarlet & yellow Opaque	Slightly bitter	Odorless	Crystalline powder	Imox 500 mg
AMX 6	Nemoxil	Scarlet & yellow opaque	Slightly bitter	Odorless	Crystalline powder	Nemel 500 mg
AMX 7	Lamox	Scarlet & ivory opaque	Slightly bitter	Odorless	Crystalline powder	Lamox 500 mg
AMX 8	Floximox	Scarlet & yellow opaque	Slightly bitter	Odorless	Crystalline powder	Floximox evans 500 mg
AMX 9	Amoxil	Scarlet & yellow opaque	Slightly bitter	Odorless	Crystalline powder	Amoxil 500 mg
AMX 10	Moxitin	Scarlet & ivory opaque	Slightly bitter	Odorless	Crystalline powder	Moxitin 500 mg

Table 3. Capsule weight

Code no	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total (g)	Total (mg)	Mean (mg)
AMX 1	0.59	0.60	0.60	0.59	0.60	0.58	0.60	0.60	0.59	0.58	0.59	0.60	0.60	0.60	0.58	0.58	0.60	0.60	0.60	0.60	11.88	11880	594
AMX 2	0.58	0.56	0.56	0.56	0.60	0.58	0.60	0.57	0.59	0.57	0.59	0.60	0.54	0.56	0.56	0.56	0.57	0.57	0.56	0.56	11.44	11440	572
AMX 3	0.59	0.58	0.61	0.55	0.59	0.61	0.58	0.58	0.57	0.55	0.57	0.61	0.62	0.52	0.60	0.58	0.58	0.58	0.62	0.60	11.69	11690	584.5
AMX 4	0.59	0.57	0.58	0.58	0.58	0.63	0.60	0.59	0.60	0.61	0.61	0.58	0.61	0.60	0.61	0.55	0.59	0.57	0.55	0.59	11.79	11790	589.5
AMX 5	0.60	0.58	0.57	0.61	0.54	0.60	0.60	0.58	0.60	0.59	0.60	0.57	0.56	0.57	0.57	0.57	0.56	0.57	0.58	0.57	11.59	11590	579.5
AMX 6	0.50	0.49	0.49	0.52	0.50	0.51	0.52	0.52	0.49	0.51	0.49	0.49	0.50	0.50	0.49	0.51	0.49	0.50	0.51	0.52	10.05	10050	502.5
AMX 7	0.59	0.57	0.59	0.59	0.57	0.59	0.58	0.59	0.60	0.56	0.57	0.60	0.57	0.56	0.55	0.55	0.59	0.58	0.59	0.53	11.52	11520	576
AMX 8	0.58	0.58	0.55	0.59	0.59	0.60	0.56	0.59	0.59	0.61	0.58	0.58	0.57	0.57	0.57	0.58	0.57	0.60	0.57	0.59	11.62	11620	581
AMX 9	0.59	0.61	0.59	0.60	0.56	0.61	0.61	0.60	0.54	0.58	0.60	0.60	0.58	0.60	0.60	0.59	0.58	0.59	0.55	0.57	11.75	11750	587.5
AMX 10	0.58	0.60	0.61	0.57	0.60	0.54	0.58	0.60	0.59	0.60	0.57	0.60	0.57	0.56	0.57	0.57	0.57	0.56	0.57	0.58	11.59	11590	579.5

Table 4. Percentage weight deviation

Code no	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
AMX 1	-2.0	-1.8	2.8	-0.9	0.4	0.1	-1.1	1.7	0.1	-0.6	-0.6	0.1	1.7	-1.1	0.1	0.4	-0.9	2.8	-1.8	-2.0
AMX 2	-3.2	0.7	2.4	-0.2	-1.4	1.0	4.1	-0.6	0.8	-3.2	-3.2	0.8	-0.6	4.1	1.0	-1.4	-0.2	2.4	0.7	-3.2
AMX 3	-2.3	0.8	1.2	-1.7	4.0	2.0	1.5	-0.2	-1.8	-0.4	-0.4	-1.8	-0.2	1.5	2.0	4.0	-1.7	1.2	0.8	-2.3
AMX 4	-2.0	-1.8	2.8	-0.9	0.4	0.1	-1.1	1.7	0.1	0.6	0.6	0.1	1.7	-1.1	0.1	0.4	-0.9	2.8	-1.8	-2.0
AMX 5	-2.3	0.8	1.2	-0.7	4.0	2.0	1.5	-0.2	-1.8	-0.4	-0.4	-1.8	-0.2	1.5	2.0	4.0	-0.7	1.2	0.8	-2.3
AMX 6	-11.3	3.3	2.5	-74.7	12.0	0.0	8.3	10.0	3.0	2.8	-11.3	3.3	2.5	-74.4	12.0	-0.0	8.3	10.0	3.0	2.8
AMX 7	0.6	2.0	-1.8	-3.4	-2.2	0.5	1.0	1.6	2.0	0.9	0.9	2.0	1.6	1.0	0.5	-2.2	-3.4	-1.8	2.0	0.6
AMX 8	0.5	2.2	1.3	-1.2	0.9	1.2	1.1	1.5	1.5	2.3	2.3	1.5	1.5	1.1	1.2	0.9	-1.2	1.3	2.2	0.5
AMX 9	0.6	2.0	-1.8	-3.4	-2.2	0.5	1.0	1.6	2.0	0.9	0.9	2.0	1.6	1.0	0.5	-2.2	-3.4	-1.8	2.0	0.6
AMX 10	1.6	-0.5	-1.2	1.3	-2.0	-1.4	-1.1	1.1	-1.5	-1.5	-1.5	-1.8	1.1	-1.1	-1.4	-2.0	1.3	-1.2	-0.5	1.6

Table 5. Result on titration method

Non reduced (blank)				Reduced			Atw (mg)	Wt of spl	% drug content
Code no	Initial (t1)	Final (t2)	Total (t2-t1=tv)	Initial (t1)	Final (t2)	Total (t2-t1=tv)			
STD	0.00	18.40	18.40	0.00	6.00	6.00			
AMX 1	0.00	18.50	18.50	6.20	18.00	6.00	593	296.7	100.8%
AMX 2	0.00	17.80	17.80	6.80	32.70	5.90	575	287.7	96.0%
AMX 3	17.80	36.50	18.70	32.70	38.70	6.00	584	292.1	102.5%
AMX 4	0.00	18.50	18.50	6.20	18.00	6.00	593	296.7	100.8%
AMX 5	7.80	36.50	18.70	32.70	38.70	6.00	584	292.1	102.5%
AMX 6	36.70	45.80	9.10	24.10	26.80	2.70	435	217.6	51.6%
AMX 7	18.40	36.90	18.50	6.0	12.20	6.20	584	292.2	99.2%
AMX 8	18.50	36.70	18.20	18.00	24.10	6.10	589	294.6	97.6%
AMX 9	18.40	36.90	18.50	6.0	12.20	6.20	584	292.2	99.2%
AMX 10	0.00	18.30	18.30	38.70	44.70	6.00	583	291.6	99.2%

Table 6. Result on disintegration time in mins and secs

Code no	1	2	3	4	5	6	Mean
AMX 1	9:30	9:30	9:28	9:30	9:32	9:35	9:30
AMX 2	8:48	8:40	8:40	8:42	8:48	8:40	8:43
AMX 3	7:00	7:05	7:00	7:01	7:05	7:00	7:01
AMX 4	7:37	7:38	7:37	7:40	7:37	7:37	7:37
AMX 5	9:00	9:01	9:00	9:00	9:00	9:01	9:00
AMX 6	11:57	11:56	11:50	11:57	11:58	11:57	11:55
AMX 7	9:25	9:25	9:28	9:25	9:27	9:25	9:25
AMX 8	9:36	9:36	9:36	9:40	9:38	9:38	9:37
AMX 9	10:50	10:50	10:55	10:50	10:50	10:50	10:50
AMX 10	9:24	9:28	9:24	9:24	9:24	9:25	9:24

Table 7. Moisture uptake result

Code no	Monday	Tuesday	Wednesday	Thursday	Friday	Monday
1 AMX	0.63g	0.65g	0.65g	0.66g	0.66g	0.67g
2 AMX	0.66g	0.71g	0.70g	0.70g	0.70g	0.71g
3 AMX	0.68g	0.68g	0.68g	0.69g	0.69g	0.70g
4 AMX	0.67g	0.69g	0.69g	0.69g	0.69g	0.70g
5 AMX	0.68g	0.68g	0.68g	0.69g	0.69g	0.70g
6 AMX	0.66g	0.67g	0.68g	0.69g	0.69g	0.70g
7 AMX	0.67g	0.68g	0.68g	0.68g	0.68g	0.69g
8 AMX	0.68g	0.67g	0.70g	0.70g	0.70g	0.71g
9 AMX	0.69g	0.69g	0.70g	0.70g	0.70g	0.71g
10 AMX	0.69g	0.69g	0.69g	0.70g	0.70g	0.71g

Table 8. Results on various tests carried out on the capsules

Code no	Mean Weight (mg)	Content uniformity		Mean disintegration (mins)	Dissolution (%) at 60mins	Mean moisture uptake (g)
		Titration method (%)	Hplc method (%)			
AMX 1	594	100.8	99.32058	9mins 31secs	70	0.65
AMX 2	572	96.0	95.91267	8mins 43secs	83	0.75
AMX 3	588	102.5	100.84734	7mins 02secs	82	0.68
AMX 4	590	100.8	108.47164	7mins 38secs	85	0.69
AMX 5	580	102.5	99.18244	9mins 00secs	69	0.69
AMX 6	503	51.6	51.51786	11 mins 56 secs	49	0.69
AMX 7	576	99.2	108.38175	9 mins 26 secs	80	0.68
AMX 8	582	97.6	106.21077	9 mins 37 secs	75	0.70
AMX 9	589	99.2	99.31958	10 mins 51 secs	82	0.70
AMX 10	580	99.2	99.08243	9 mins 25 secs	81	0.70

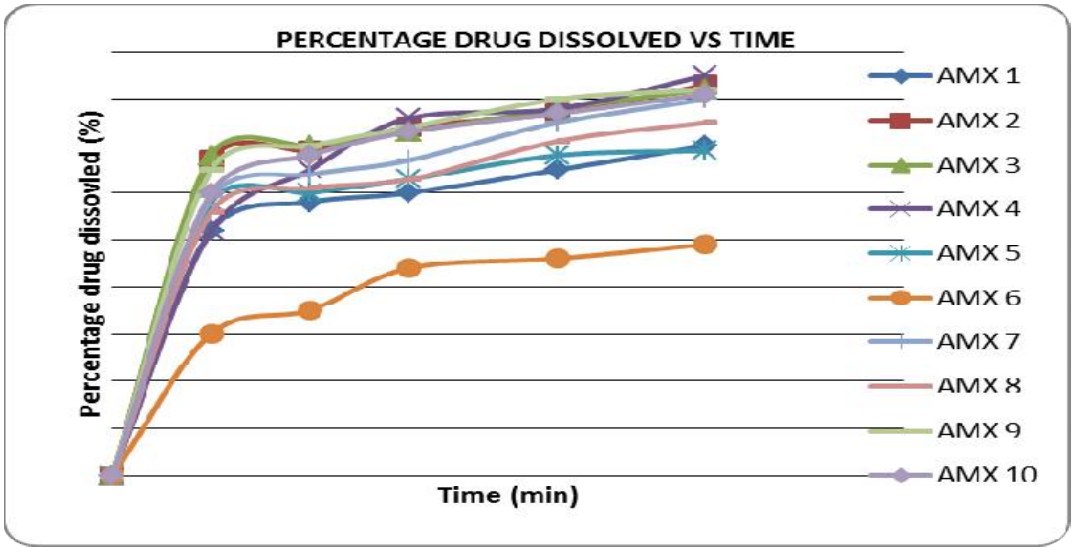

Fig. 3. Dissolution Profile of Different Brands of Amoxicillin Trihydrate

5. CONCLUSION

From this study and the various results obtained, it can be said that the majority of the commercially available brands of Amoxicillin Trihydrate are up to pharmaceutical standard of quality and are safe for use by consumers.

6. RECOMMENDATIONS

The manufacturers are advised to take into considerations the official standards (BP, EP, and USP/NP) and make sure they are adhered to during production. The quality control personnel must be of a qualified and trained individual and should assist in all stages of production by building in good manufacturing practice in terms of checking, monitoring, evaluating and documenting for good, safe and efficacious products. Critical steps of manufacturing process and all significant changes during any of the manufacturing stages must be validated. Correct materials, containers and labels must be made available. Usage of approved procedures and instructions must be adhered to for suitable storage and transport facilities must also be made available. Records should be made during manufacturing to ensure all steps required by the defined procedure have been taken and there is no violation of the quality and quantity of the products. All complaints should be examined because of the quality defect investigated and appropriate measures taken to prevent any further recurrence.

CONSENT

Not applicable.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been carried out according to the regulations laid down by Pharmaceutical Council of Nigeria examined and approved by Committee on Research and Publication of the Faculty of Pharmacy, Igbinedion University Okada, Benin City, Nigeria.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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