IJPSR (2016), Vol. 7, Issue 5 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 24 November, 2015; received in revised form, 16 January, 2016; accepted, 07 February, 2016; published 01 May, 2016

EVALUATION OF THE QUALITY OF SOME ANTIBIOTICS DISTRIBUTED IN ACCRA AND LAGOS

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Key words:

Azithromycin, Erythromycin, Clindamycin, HPLC, *In-vitro* Dissolution, Substandard

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ABSTRACT: The persistent prevalence of poor-quality medicines in resource-limited settings has contributed significantly to the alarming global trends in antibiotic resistance. Antibiotics are among the most used, abused and counterfeited medicines and therefore require regular monitoring and surveillance to provide reliable data for proper healthcare delivery. This study evaluated the quality of a total of 45 samples of Azithromycin, Erythromycin and Clindamycin distributed in Accra and Lagos by HPLC for active pharmaceutical ingredient (API) content and *in-vitro* dissolution for bioavailability. The results revealed that although all the samples contained the requisite API, only 27% were compliant with US Pharmacopoeia requirements for content. For Azithromycin and Clindamycin samples, the presence of excess API was the cause for non-compliance. Regardless of the high failure rate with respect to content, all Azithromycin samples exhibited good dissolution profiles, while 67% of Clindamycin and 36% of Erythromycin were compliant with in-vitro dissolution. These findings suggest that the population in the study sites and possibly in other parts of the sub regionis exposed to substandard antibiotics. Comprehensive measures by Drug Regulatory Authorities to monitor and enforce regulations governing production, importation, registration and storage of essential medicines are needed to address the problem.

INTRODUCTION: The application of antibiotics in the fight against infection and in other medical procedures such as surgery and chemotherapy makes them one of the most commonly prescribed medicines in health facilities across the world. The susceptibility of children to infections, especially upper respiratory tract infection, also contributes to the high demand for antibiotics. However, this essential therapeutic group of medicines is under serious threat of resistance. The highlights of the WHO 2014 global report on antimicrobial resistance is on antibiotics, and it reveals an unfolding universal pandemic with frantic calls for a comprehensive collaborative effort to contain the situation [1]. While antibiotic resistance is a natural phenomenon, the problem is exacerbated by a myriad of factors including misuse and abuse of antibiotics, poor sanitary conditions, use of poor-quality medicines and inadequate regulation and surveillance. Key findings from the 2015 WHO report on the worldwide country situation suggest that in spite of commitment by all regions to address the problem,

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.7(5).1991-00

Article can be accessed online on: www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.7 (5).1991-00

there are still significant challenges in tracking antibiotic resistance [2].

Typically, in the low- and middle-income regions, weak regulatory systems and lack of law enforcement promote the distribution of poor-quality medicines. The administration of poor quality medicines has devastating consequences on primary healthcare delivery. These include the risk of development of resistance, treatment failures and even death. Children are more likely to be affected by poor-quality antibiotics because their immune systems are not fully developed and therefore are more prone to infections. Many studies regarding the quality of antimicrobial medicines have reported the circulation of a wide range of counterfeit and substandard medicines in many parts of Asia and Africa. All categories of antibiotics including old, common and new therapies such as the penicillins, macrolides, tetracycline, sulphonamides, quinolones and aminoglycosides have been affected [3, 4, 5]. These medicines have failed for a variety reasons including: no active pharmaceutical ingredient (API), too much or too little API, wrong API, inappropriate labelling, expired medicine, low bioavailability, failed disintegration and excessive degradation.

Accra (Ghana) and Lagos (Nigeria) are two major cities with similar socio-economic settings in the West Africa sub region. Nigeria is known to have a long history of counterfeit antibiotics [6]. The National Agency for Food and Drug Administration and Control (NAFDAC), set up to with the mandate to create a fake-drug-free environment in Nigeria is still grappling with lack of enforcement of existing drug laws. The inability to close the unmonitored, unlicensed and unregulated open markets that serve as popular drug distribution centres has been identified as a major challenge in the fight against poor-quality drugs [6, 7]. According to Ghana's Food and Drugs Authority (FDA), about 70% of the country's pharmaceutical needs are imported. Lack of capacity to carry out adequate surveillance at the entry points has resulted in the influx of poor-quality medicines whose quantities are even difficult to estimate. Apart from the health implications, such a heavy reliance on foreign medicines also threatens to cripple local pharmaceutical manufacturing companies. The print and electronic media often provide anecdotal reports on recall or confiscation of medicines with compromised quality by the FDA [8, 9]. Two recent research reports also indicate the presence of substandard antibiotics on the Ghanaian market [10, 11].

Reliable data on the prevalence of poor-quality medicines is critical in informing the appropriate measures needed to address the problem. Most of the recent WHO-sponsored and other drug quality studies have focused on antimalarials. Therefore in the present study, we decided to consider antibiotics as another important class of antimicrobials. According to the FDA, antibiotics are the largest prescribed medication in the books of the Ghana Health Service, and the demand for them cannot be met on a consistent basis [9]. A selection of various dosage forms of Azithromycin, Erythromycin and Clindamycin distributed in Accra (Ghana) and Lagos(Nigeria) were evaluated for their quality with respect to the API content and bioavailability.

The criteria for the selection of the products were their inclusion in the countries' essential medicine lists, high prescription rateand availability of reference standard. Azithromycin and Erythromycin are among the most commonly used antibiotics, especially for paediatric administration, and Clindamycin now has renewed interest after clinical trials of successfully using it to treat over 500 patients of malaria infection in Africa, South America, and Asia [12, 13].

MATERIALS AND METHODS:

Sampling:

The medicine samples were selected based on their inclusion on the WHO Essential Medicine list, high prescription rate, availability of reference standard and paucity of information on recent medicine quality studies. They consisted of available formulations of Erythromycin, Azithromycin and Clindamycin purchased from distributors, pharmacies, and licensed chemical stores in the Accra municipality in Ghana and the Mushin Local Government Area of Lagos, Nigeria. Sampling design was mainly by convenience since it did not

follow a list of medicine outlets in defined areas. Samplers constituted members of the research team who posed as normal shoppers buying medication. In instances where a prescription was required or large and different samples were being purchased from the same seller it was necessary to explain that they were for research purposes. In such cases, a few sellers responded with some reservation. A total of 45 samples was obtainedbetween September 2012 and April 2013. They were stored in a cold dry place as prescribed by the manufacturers prior to analyses and were analysed within the period of their shelf lives. Details of all the samples are presented in **Table 1**.

TABLE 1: LIST OF ANTIBIOTICS COLLECTED FROM ACCRA AND LAGOS

Active ingredient	Dosage forms	Batch No.	Country of origin
Azithromycin (25/45, 56%)			
GAa1	Tablets	R51002 R	India
GAa2	Capsules	RC 109	Ghana
GAa3	Capsules	210022	England
GAp1	Oral Suspension	CH1841	Romania
GAa4	Tablets	MD2002	Ghana
GAp2	Oral Suspension	SVA 293	Bangladesh
*GAp3	Oral Suspension	130400	Italy
GAa5	Capsules	0107K	Ghana
NAa1	Tablets	2892	India
NAa2	Tablets	ROYH0003	India
NAa3	Capsules	101112	India
NAp1	Oral Suspension	701	India
NAa4	Tablets	ET-1C04	India
NAa5	Tablets	AZF 01	India
NAa6	Capsules	2005	Nigeria
NAp2	Oral Suspension	441196	Ecuador
NAp3	Oral Suspension	1601	India
NAa7	Capsules	Z1101	Nigeria
NAa8	Capsules	110229	India
NAp4	Oral Suspension	11274	India
NAa9	Capsules	1012	India
NAa10	Capsules	RA2001	India
NAa11	Capsules	120516	China
NAa12	Tablets	20111201	Nigeria
NAp5	Oral Suspension	131201	India
Erythromycin (14/45, 31%)			
GEa1	Tablets	0303L	Ghana
NEa1	Tablets	12220	India
NEa2	Tablets	HE12D09	Nigeria
NEa3	Tablets	BB06523	Malaysia
NEa4	Tablets	RA 2004	India
NEa5	Tablets	120512	China
NEa6	Tablets	9L120	Pakistan
NEa7	Caplets	RG1202	Nigeria
NEa9	Tablets	103	India
NEa10	Tablets	24	India
NEa11	Tablets	LNHT - 005	India
NEa12	Tablets	EDTP - 05	Nigeria
NEa13	Tablets	610675	India
NEa14	Tablets	110101	China
Clindamycin (6/45, 13%)			
GCa1	Capsules	210014	England
GCa2	Capsules	182431	England
GCa3	Capsules	GH09202	India
GCa4	Capsules	0848003	France
NCa1	Capsules	20110105	China
NCa2	Capsules	A014803	France

G = Ghana; N = Nigeria; A = Azithromycin; E = Erythromycin; C = Clindamycin; a = adult; p = paediatric
*Sample GAp3 had a NAFDAC registration number on its pack

Reference standards:
Reference standards were acquired from Anuh Pharma Ltd and comprised Azithromycin batch number A2095A10 with % purity of 95.71; Clindamycin HCl batch number 0032009086 with % purity of 89.39;Erythromycin batch number EB003007 with % purity of 89.34.

Analytical Techniques:
Visual inspection was done to check for signs of falsification. Qualitative test for the presence of the requisite API was done using either available colour reaction test or the HPLC retention time. Quantitative API content was assayed by HPLC methods. *In-vitro* dissolution test was used to determine the bioavailability of the medicines.

Visual inspection:
The packaging and formulations were respectively examined for defects and signs of discolouration, deterioration or other physical disfiguration. Dates of manufacture and expiration of each sample were checked and recorded.

Qualitative test:
Erythromycin API was identified in accordance with the International Pharmacopoeia identification test C method, used in the qualitative test of Erythromycin Stearate [14]. For Azithromycin and Clindamycin, their requisite APIs were detected from the HPLC retention times in comparison with those of their reference standards.

HPLC Assay:
Validated methods, based on HPLC assay procedures described in the United States Pharmacopoeia (USP) and other literature were employed in the determination of API content [14, 15, 16, 17]. **Table 2** presents details of the modified procedures carried out on an Agilent Technologies 1200 series HPLC system equipped with a quaternary pump, an auto-sampler and Diode Array Detector (DAD). A calibration curve for each of the three reference standards was prepared under the experimental conditions described in **Table 2**. Briefly, 50µl of various concentrations of Azithromycin RS (0.3542, 0.4048, 0.4554, 0.5060, 0.5566, 0.6072 and 0.6578mg/ml); Erythromycin RS (0.7, 0.8, 0.9, 1.0, 1.1, 1.2 and 1.3 mg/ml) and 25µl of Clindamycin RS (0.7, 0.8, 0.9, 1.0, 1.1, 1.2 and 1.3 mg/ml) were injected into the HPLC machine and their respective Areas Under the Curve (AUCs) were recorded. Each RS concentration was analysed in six replicates and the average AUC was plotted against their respective concentrations to give the graph of linear calibration. Employing the equation of a straight line obtained from the calibration curves, the concentrations of the various APIs of the antibiotics were determined. **Fig. 1** shows chromatograms of each RS and a corresponding medicine sample.

***In-vitro* Dissolution Test:**
The *in-vitro* dissolution test was carried out in accordance with the USP on a Vanguard Pharmaceutical Machinery LID-8 Dissolution Tester. For Azithromycin and Erythromycin tablets/capsules, the Paddle apparatus (USP Type 2) was used. The dissolution medium for Azithromycin was 0.10M Na_2HPO_4, pH 6.0 + trypsin and 0.05M Na_2HPO_4, pH 6.8 for Erythromycin. The Basket apparatus method (USP Type 1) was used for Clindamycin capsules in a dissolution medium = 0.05M Na_2HPO_4, pH 6.8. The respective HPLC assays were used in the quantification of the dissolved API.

TABLE 2: EXPERIMENTAL CONDITIONS FOR THE HPLC ASSAY OF API

Experimental condition	Azithromycin		Erythromycin		Clindamycin	
	USP 2010 [15]	Modified method	Shaikh Method [16]	Modified Method	Japanese Pharmacopoeia Method [17]	Modified Method
Column	γ-Alumina or Zirchrom-PBD (4.6 x 250mm; 3µm)	Xterra MS C18 (150 x 4.6 mm; 5µm)	Waters Xterra RP18 (250×4.6mm, 5µm)	Xterra MS C18 (150 x 4.6 mm; 5µm)	octadecylsilanized silica gel column (250 x 4.6 mm; 5µm)	octadecylsilanized silica gel column (250 x 4.6 mm;5µm)
Mobile Phase	14mM K_3PO_4; 20mM KOH; 29%	0.05M K_2HPO_4 buffer:	30mM K_2HPO_4:acetonitrile (50:50, v/v) pH 9.0	0.05M K_2HPO_4 buffer:	0.05M KH_2PO_4 buffer: acetonitrile	0.025M KH_2PO_4 buffer: acetonitrile

	acetonitrile (pH 11)	acetonitrile (40:60, v/v) pH 8.2		acetonitrile (40:60, v/v) pH 8.2	(55:45, v/v) pH 7.5	(55:45, v/v) pH 7.5
Injection Volume	50µL	50µL	-	50 µL	30 mL	25 µL
Flow rate	1.0mL/min	1 ml/min	1.7 ml/min	1 ml/min	flow rate adjusted to give Rt of 10 minutes	1 ml/min
Wavelength of detection	dual coulometric electrodes	DAD at 210nm	215 nm	DAD at 210 nm	UV at 210nm	DAD at 210nm
Temperature	-	30°C	50°C	30°C	25°C	30°C
Average Retention time	10.25 min	7.995 min	11.5 min	3.285 min	10 min	7.205 min

Validation:

Accuracy, precision, linearity and specificity parameters were evaluated for all the various determinations. Validation parameters including precision (RSD values), linearity (R^2 values), accuracy (% recovery) and specificity (retention times) were evaluated for all the various determinations (n = 6).

RESULTS:

A total of 45 samples was obtained and analysed. With respect to branding, Nigeria exhibited far greater variety of brands of Azithromycin (14) and Erythromycin (13) but fewer Clindamycin (2) than Ghana. Only 2 brands were common to both countries - *Zithromax* (Azithromycin) and *Dalacin* (Clindamycin). Although the *Zithromax* oral suspension collected in Ghana was manufactured by Pfizer, Italy, it had a NAFDAC registration number on its pack while the Nigerian collection was from Pfizer, India. *Dalacin* from both countries was also from Pfizer, France. Only one brand of Erythromycin was found in Ghana.

All attempts to obtain other brands were unsuccessful. Both countries rely heavily on imported antibiotics - 35 brands were foreign while 10 were locally manufactured. The source of the imported medicines differed widely for the two countries. Regarding registration status, all samples from Nigeria had their registration numbers printed on the package while only 2 samples from Ghana (one of them with NAFDAC registration number) were registered. Visual inspection of packaging revealed that all of the medicines were well-packaged and the visible characteristics normally associated with counterfeits were not observed. They were labelled with dates of manufacture and expiration as well as batch numbers. On further examination, the formulations were found to be undamaged, smooth and of uniform colour.

All the Erythromycin samples tested positive for the presence of Erythromycin stearate by colour testwhile Azithromycin and Clindamycin APIs in the formulations were both identified by their retention times on HPLC.The average retention times for Azithromycin RS and formulations were 6.816 and 6.930 minutes respectively. For Clindamycin, the respective average retention times for the RS and formulations were 7.210 and 7.533 minutes. Sample chromatograms are presented in **Fig. 1**.

Based on the results of the HPLC analysis, the medicine samples were grouped into two main categories. Those that complied with USP standards were tagged compliant (C), while those that did not comply were tagged non-compliant (NC). However, there were a few samples which found to be marginally compliant (±2) and were therefore tagged (MC). According to the USP 2010, Azithromycin tablets or capsules should contain not less than 90.0% and not more than 110.0% of the labelled amount of Azithromycin API; Erythromycin Stearate tablets and Clindamycin Hydrochloride capsules should contain not less than 90.0 % and not more than 120.0 % of the labelled amount. The results are presented in **Table 3**.

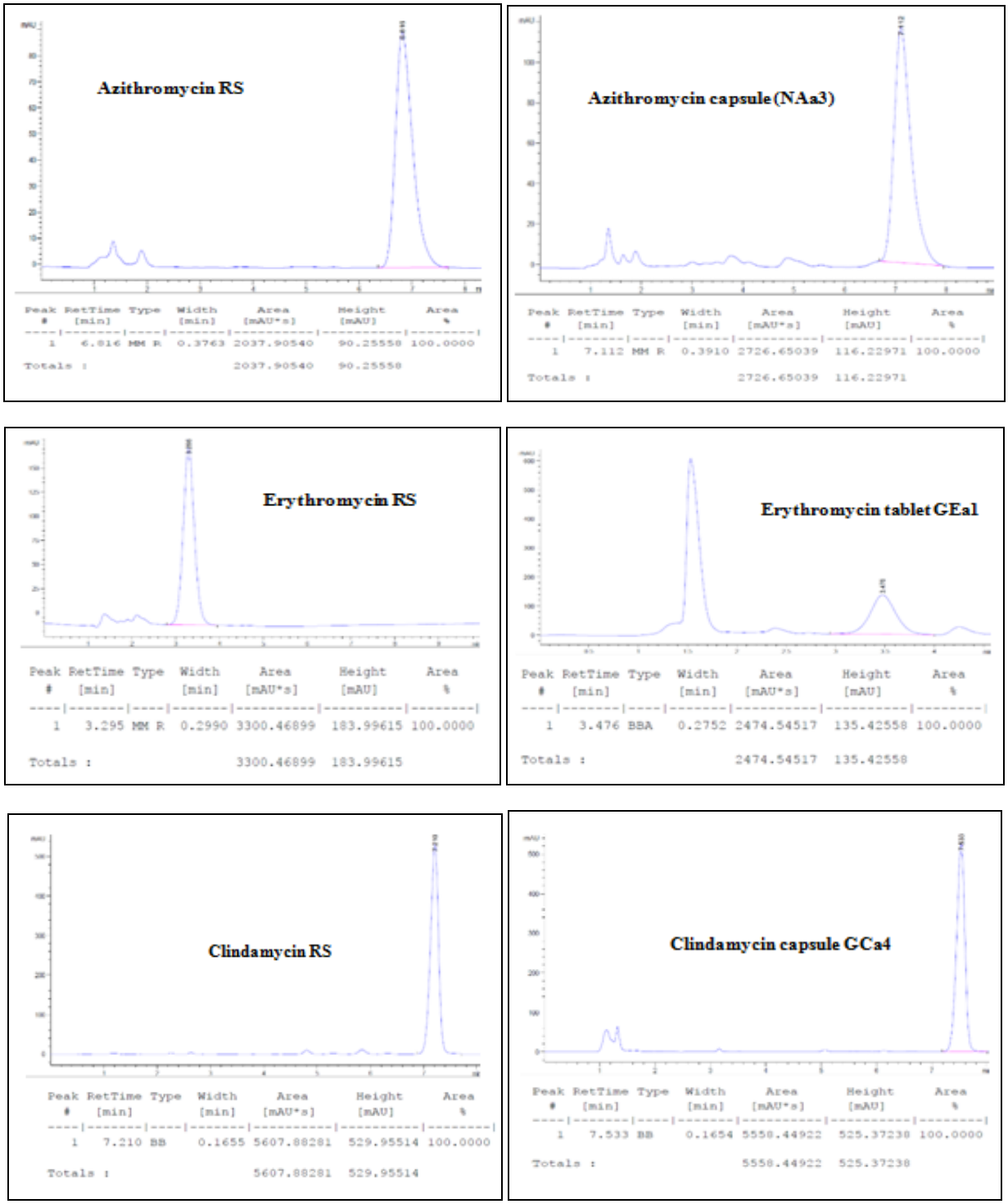

FIG. 1: CHROMATOGRAPHIC PROFILES OF AZITHROMYCIN, ERYTHROMYCIN AND CLINDAMYCIN RS ANDTHEIR CORRESPONDING MEDICINE SAMPLES

A total of 37 samples comprising all the tablets and capsules dosage forms were evaluated for their dissolution profiles and their performance assessed per USP requirements. Samples that fell within the acceptable limits were considered compliant whereas those with low dissolution profiles were tagged noncompliant. Marginally compliant samples were described as MC. According to USP specifications, not less than 75% of the labelled amount of Erythromycin Stearate should be dissolved in 120 minutes; not less than 80% of the labelled amount of Clindamycin hydrochloride should be dissolved in 30 minutes; not less than 80% of the labelled amount of Azithromycin tablets should be dissolved in 30 minutes and not less than 75% of labelled amount of Azithromycin

capsule should be dissolved in 45 minutes [15]. The level of compliance of the 37 samples are shown in **Table 3**.

TABLE 3: RESULTS OF HPLC ASSAY AND *IN-VITRO* DISSOLUTIONTESTOF ANTIBIOTICS

Sample	Manufacturer's label claim (mg)	% Assay ± rsd (n=6)	USP standard	% Dissolution ± rsd (n=6)	USP standard
Azithromycin			**90-110%**		**75% for tablet 80% for capsule**
GAa 1	250	94.62 ± 0.02	C	100.44 ± 0.4	C
GAa 2	250	120.53 ± 0.03	NC	105.27 ± 0.8	C
GAa 3	250	129.16 ± 0.05	NC	116.09 ± 4	C
GAa 4	250	96.03 ± 0.04	C	113.93 ± 0.4	C
GAa 5	250	121.91 ± 0.06	NC	93.64 ± 0.8	C
NAa 1	250	103.92 ± 0.05	C	96.84 ± 3	C
NAa 2	250	103.36 ± 0.04	C	107.94 ± 0.3	C
NAa 3	500	127.99 ± 0.03	NC	83.37 ± 0.5	C
NAa 4	500	129.10 ± 0.06	NC	110.23 ± 1	C
NAa 5	500	121.45 ± 0.03	NC	112.53 ± 0.9	C
NAa 6	250	97.83 ± 0.05	C	94.31 ± 0.6	C
NAa 7	250	125.33 ± 0.04	NC	96.02 ± 0.4	C
NAa 8	250	143.73 ± 0.05	NC	94.00 ± 1	C
NAa 9	250	122.38 ± 0.06	NC	88.15 ± 05	C
NAa 10	250	135.56 ± 0.03	NC	95.38 ± 0.4	C
NAa 11	500	127.72 ± 0.05	NC	86.58 ± 5	C
NAa 12	250	109.85 ± 0.02	C	108.29 ± 0.5	C
NAp 1	200	162.36 ± 0.03	NC	-	-
NAp 2	200	162.94 ± 0.07	NC	-	-
NAp 3	200	152.25 ± 0.05	NC	-	-
NAp 4	200	107.33 ± 0.03	C	-	-
NAp 5	200	132.82 ± 0.06	NC	-	-
GAp 1	200	159.16 ± 0.03	NC	-	-
GAp 2	200	105.82 ± 0.04	C	-	-
GAp 3	200	137.42 ± 0.04	NC	-	-
Erythromycin			**90-120%**		**75%**
GEa 1	250	47.82 ± 0.01	NC	53.16 ± 5	NC
NEa 1	500	55.46 ± 0.09	NC	53.18 ± 4	NC
NEa 2	500	84.92 ± 0.001	NC	74.61 ± 4	MC
NEa 3	500	83.92 ± 0.11	NC	85.96 ± 2	C
NEa 4	500	59.83 ± 0.02	NC	53.07 ± 3	NC
NEa 5	500	60.22 ± 0.03	NC	74.98 ± 2	MC
NEa 6	500	79.15 ± 0.01	NC	68.68 ± 2	NC
NEa 7	500	93.44 ± 0.23	C	96.49 ± 1	C
NEa 9	500	83.08 ± 0.06	NC	67.20 ± 0.6	NC
NEa 10	250	65.32 ± 0.003	NC	95.03 ± 2	C
NEa 11	500	85.33 ± 0.03	NC	83.82 ± 0.3	C
NEa 12	500	88.74 ± 0.01	MC	103.46 ± 1.0	C
NEa 13	500	107.02 ± 0.01	C	64.51 ± 0.9	NC
NEa 14	500	72.52 ± 1.13	NC	65.30 ± 0.3	NC
Clindamycin			**90-120%**		**80%**
GCa1	150	139.22 ± 0.01	NC	85.30 ± 2	C
GCa2	150	142.81 ± 0.01	NC	83.04 ± 2	C
GCa3	150	134.66 ± 0.003	NC	81.21 ± 2	C
GCa4	150	91.15 ± 0.10	C	74.06 ± 5	NC
NCa1	300	101.15 ± 0.08	C	85.41 ± 5	C
NCa2	150	134.01 ± 0.2	NC	79.95 ± 2	MC

The validation parameters of the analyses are summarized in **Table 4**.

TABLE 4: RESULTS OF VALIDATION PARAMETERS

Validation parameter	Azithromycin	Erythromycin	Clindamycin
Precision (RSD)	0.041070492	0.124971794	0.067554377
Linearity(R^2)	0.9987	0.9950	0.9982
Slope	4160.4	1272.5	5478.7
Intercept	-35.2	81.9	88.5
Specificity (Av. Retention time)			
Medicine Sample API	6.930 minutes	3.476 minutes	7.533 minutes
Reference Standard	6.816 minutes	3.295 minutes	7.210 minutes

DISCUSSION: The results of the HPLC assay for API content showed that only 12 (27%) out of the 45 samples were compliant with USP requirements. They comprised 4 out of the 13 (27%) samples collected from Accra and 8 out of the 32 (25%) samples from the Lagos collection. The compliant samples consisted of 8 (32%) Azithromycin, 2 (14%) Erythromycin and 2 (33%) Clindamycin. There were 8 brands of Azithromycinpaediatric formulations among the collections and only 2 of these, one from each country, were compliant. Two categories of non-compliant samples were identified – those with low API concentrations and those containing excess API. All non-compliant Erythromycin samples contained insufficient API. The only brand of Erythromycin obtained in Accra contained the least API (<50%) among all the samples. Ten other Erythromycin samples had API content between 50 and 88% while sample NEa12 was marginally compliant (88.74%). For Azithromycin and Clindamycin samples, the presence of excess API was the cause of non-compliance. Four Clindamycin samples contained >134% API while 17 Azithromycin samples, including 6 paediatric suspensions presented with API quantities >120%.

One of the critical quality indicators of a given medicine is its API content. If the latter is in specification with pharmacopoeial limits, the medicine is judged to be of good quality. According to recent definitions from the WHO, substandard medicines are pharmaceutical products produced by legitimate manufacturers which do not meet their quality standards and specifications. Falsified medicines like substandard ones, also do not meet quality specifications; the distinction is that there is a deliberate intent to breach regulatory requirements. Thus, falsified medicines may contain no API at all, the wrong API, unacceptably high levels of impurity or inappropriate packaging [18, 19]. The findings from this study confirm that all the samples analysed contained the requisite API, albeit, in incorrect amounts in the majority of them (63%). Since it is difficult to allude to the incorrect API content as deliberate, and the visible characteristics usually associated with falsified medicines were also not observed, the non-compliant samples can be characterized as substandard medicines.

Several studies have reported on substandard antibiotics as well as other essential medicines, attributing the cause to the effects of either poor manufacturing practices or poor storage and transport conditions or both. Reports on the presence of insufficient API are however more common than those on excess API. It is difficult to explain why manufacturers will include more than the maximum allowable limit. While too little API may result in treatment failure and parasite resistance, too much API could lead to toxicity in patients and the implications are even more crucial for paediatric formulations.

The API content analysis was complemented with dissolution testing to provide information on the extent of API release sincea medicine's bioavailability is also considered an important parameter in its efficacy and quality. All the Azithromycin tablets and capsules passed the dissolution test with >80% drug release, regardless of the high level of non-compliance (68%) with respect to API content. Possibly, the presence of excess API in the non-compliant samples may have positively influenced the extent of drug release. Similar observations were made with the Clindamycin samples. Three out of the 4 samples that contained excess API passed the dissolution test while 1 was marginally compliant. However, the Erythromycin samples gave mixed results – of the 11 samples that failed the assay test due to

insufficient API, 6 were non-compliant, 3 were compliant while 2 were marginally compliant with the dissolution test. One sample that was compliant with assay gave a poor dissolution profile and only sample NEa7 was in specification with both assay and dissolution tests. Erythromycinis reported to exhibit potential bioavailability problems [20]. These observations are therefore a likely consequence of drug-excipient or excipient-excipient interactions and can be addressed by enforcing the mandatory stability studies during formulation development.

The quality of the imported medicines was similar to that of the local ones. Since all the samples were analysed within their shelf lives, the manufacturing process may have had a greater influence on the outcome of the study than exposure to the tropical climatic conditions. Although it was not determined how long the imported samples have been stored under these conditions, the sensitivity of the domestic and foreign samples was not very different. One out of the 4 made-in-Ghana samples (GAa4) passed both tests. Erythromycin was scarce in Ghana during the sampling period; the only sample obtained (GEa1) was locally manufactured and it was found to be non-compliant with both assay and dissolution. Two samples manufactured in Nigeria (NAa12 and NEa7) were fully compliant with both tests. Sample NEa12 was fully compliant with dissolution but marginally compliant with assay.

CONCLUSION: This study identified substandard antibiotic samples in circulation in Accra and Lagos. Majority of the Clindamycin and Azithromycin samples analysed contained excess API but all showed acceptable dissolution profiles. Erythromycin samples on the other hand, generally had insufficient API as well as poor dissolution. The use of the two countries as a case study was based on their socio-economic similarities and the findings are possibly not limited to the study sites but likely to be the case in most resource-limited parts of developing countries.

The heavy over-reliance on import coupled with the widely different sources of foreign medicines is a major contributory factor to the influx of substandard medicines on our market. The promotion of domestic production to meet local medical and pharmaceutical requirements will reduce importation of essential medicines and also enable the National Drug Regulatory Authorities (NDRAs) within the sub region to carry out better monitoring, regulation and surveillance in their respective countries. Furthermore, it is recommended the NDRAs coordinate their activities such that they have common sources of imports from a few credible manufacturers. This will help strengthen their capacity to monitor and enforce regulations governing the production, importation, registration,storage and distribution of medicines as well as consumer education to be able to provide better healthcare systems.

ACKNOWLEDGMENTS: The study was carried out in the laboratories of the Department of Chemistry and School of Pharmacy, University of Ghana, Legon. We thank the University of Ghana for graduate assistance to Mr Horatio Akpoviri Egbo.

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How to cite this article:
Osei-Safo D, Egbo HA, Nettey H, Konadu DY and Addae-Mensah I: Evaluation of the Quality of Some Antibiotics Distributed In Accra and Lagos. Int J Pharm Sci Res 2016; 7(5): 1991-00.doi: 10.13040/IJPSR.0975-8232.7(5).1991-00.