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Quality Control Assay of Ampicillin Brands of Capsules in Onitsha Market, Southeastern Nigeria

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Abstract: The ampicillin content (5) if ten different brands of ampicillin capsules in circulation in the onitsha central drug market were determined. Two analytical methods were used; iodiometric and UV-visible spectrophotometric analyses. The results showed that 60% of the different brands of capsules analyzed were within Bp stipulation values where as 40% of the remaining brands of capsules were blow the Bp stipulated values. Two brands; miracillin and polfa brands of ampicillin capsules were completely out of the range of stipulated values. These two brands are therefore, substandard, adulterated and the prevalence of fake, adulterated and substandard ampicillin capsules in this market is a great damager to the health of the entire people of West Africa sub region that depend entirely on this market for their pharmaceuticals.

Key words: Ampicillin capsules, brand, substandard, Fake, adulteration

INTRODUCTION

Ampicillin is a broad-spectrum antibiotics it is a sulphur-containing antibiotics that is active against gram-positive and gram-negative bacteria (Kirkpatrick, 1980; British Pharmacopoeia, 1993). The precursor of this sulphur-containing drug is penicillin G. penicillin G, is one of the earliest antibiotics in use in the medical world since the second world war (Bernard, 1980). Ampicillin is produced through the chemical modification of penicillin G. Ampicillin is widely used in its capsular form as broad-spectrum antibiotics in Nigeria and other West Africa sub-region of Togo, Ghana, Cameroon, Benin republic, Mali, Chad. The specification for each capsule of ampicillin should not contain less than 95.5% and not more than 107.5% ampicillin as its content and label claims (Atuenyi, 1991; British Pharmacopoeia, 1988). For ampicillin capsules to be therapeutically effective, the pharmaceutical dosage forms must contain the stated amount of the active chemical substances as the official standard (British Pharmacopoeia, 1993; 1988). Due to the economic and health implications of substandard, adulterated and fake ampicillin capsules on the people of West Africa sub-regions, this study is therefore designed to evaluate the quality of different brands of ampicillin capsules in circulation in the Onitsha drug central market.

MATERIALS AND METHODS

Sample collection: Ten different brands of ampicillin capsules (250 mg dose) were procured at the Onitsha drug central market in Anambra state, Nigeria. All chemical used were analytical grade reagents, from BDH chemicals, England, a chemical reference material pure ampicillin trihydrate power was supplied by a pharmaceutical company Nichben pharmaceutical industries, Ltd Awo-Omma, Oru L.G.A, Imo State, Nigeria.

Sample preparation: Ten capsules contained in each of the ten different brands of ampicillin capsules procured there decapsuled manually. The content of each was mixed together to obtain a composite sample of each brand.

Iodiometric analysis (British Pharmacopoeia, 1988; Willard *et al.*, 1974; Skog and West, 1980): A composite sample of inlaks brand measuring 168.4 mg equivalent to 132 mg pure ampicillin trihydrate power was weighed out and taken into 100 mL flask. Ten mL of distilled water was added into the flask, shaken vigorously to ensure complete dissolution. The solution thus formed was filtered into a 100 mL volumetric flask using what man N0.40 Filter paper. The Filtrate was made up to 100 mL mark with distilled water. The above procedure was used

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exactly in the preparation of solutions of each brand using equivalent weight of each brand. The equivalent weight of each brand used was Ranbaxy 171.3 mg, Helm 152 mg, polfa 166.4 mg, miracillin162.5 mg, Sojy 147.6 mg, plva148.5 mg Aurobindo 161.5 mg, Lyka 1516 mg and Britlodge 209.5 mg respectively. From each of the branch solutions; 6 mL was pipette into a labeled flask; 6 mL of lm Na OH solution was added stoppered and allowed to stand for 2 min. Thereafter, 6 mL of 1.2m HCL solution was added, shaken thoroughly, allowed to stand for another 2 min. 20 mL 0.01m iodine solutions were added, stoppered, allowed to stand in a dark cupboard for 15 min. At the end of 15 min duration the solution was titrated against 0. 01m solution of sodium thiosulphate freshly prepared, using starch mucilage as indicator. Each titration was repeated three times. A control titration was carried out as described above in which the sample solution and NaOH solution were excluded.

A standard solution of ampicillin trihydrate was prepared using 132 mg ampicillin trihydrate pure sample. This standard ampicillin trihydrate solution was analyzed in the same manner as described for the samples above.

UV-visible spectrophotometric analysis, (Alfonson, 1980; United States Pharmacopoeia, 1990; Olamalam, 1988): A composite sample of inlaks brand 263 mg equivalent weight was weighted out and taken into a 100 mh flash. The solution preparation was carried out using the same procedure described for iodiometric titration.

Each of the remaining nine brands solutions was prepared using equivalent weight of each brand thus; Ranbaxy 207. 6 mg, Helm 238. 1 mg, polfa 260 mg, miracillin 253.9 mg, soly 231. mg, plva 231.9 mg, lyka 326.8 mg, aurobindo 251.9 mg and Britlodge 327.5 mg, respectively.

From each of the brand solutions, 6 mL was pipetted into a labeled 100 mL flask and 50 mL sorbitol reagent was added. Each of the solutions was heated at 60°C for 10 min and allowed to 1001. A solution of 1m NaOH, 6 mL was added to each of the solution, allowed standing for 2 min each. Therefore was measured at 322 mm, Using UV-visible spectrophotometer (Unicam mode 1320).

Ampicillin trihydrate solution used as standard was prepared using 206.2 mg ampicillin trihydrate pure sample. The prepared solution was analyzed in the same manner and procedure described for each of the brand solutions.

RESULTS AND DISCUSSION

The results of the analyses are presented in Table 1 and 2, respectively.

Table 1: Ampicillin content of ten different brands of ampicillin capsules obtained using iodiometric analysis

Brand name	% Ampicillin
Standard sample	100±1.84
Inlaks	101.92±4.11
Ranbaxy	98.50±4.71
Helm	99.10±4.07
Polfa	78.32±6.79
Miracillin	04.17±2.94
Sojy	99.52±2.94
Plva	98.76±2.85
Aurobindo	85.41±3.540
Lyka	98.26± 4.26
Britlodge	90.20±3.57

Values are means±standard deviation of three determinations

Table 2: Ampicillin content of ten different brands of ampicillin capsules using uv-visible spectrophotometric analysis.

Brand name	% Ampicillin
Standard sample	100±0.208
Inlaks	101.98±0.208
Ranbaxy	98.60±0.214
Helm	99.84±0.427
Polfa	79.09±0.427
Miracillin	05.90±0.427
Sojy	99.80±0.427
Plva	98.97±0.427
Aurobindo	94.95±0.427
Lyka	18.49±0.214
Britlodge	95.50±0.398

Values are means±standard deviation of three determinations

Table 1 showed that the ampicillin capsules brand inlake yielded the highest ampicillin 101.98% followed by helm brand 99.84% ampicillin. The brand miracillin yielded the lowest ampicillin (5%). From Table 1 was observed that it is only the inlak brand of ampicillin capsules is within the upper limit of content specification of 107.5% (British Pharmacopoeia, 1988). It was only six out of the ten brands that contain ampicillin content that falls slightly above the lower limit of 92.5% (5. 9,). Two brands; miracillin and polfa were below the ampicillin content specification of 92.5-107.5%.

Table 2 showed the mean ampicillin content (s) of the ten different brands of ampicillin capsules analyzed using UV-visible spectrophotometer from Table 2, it was observed that the results were comparable to that obtained using iodiometric analytical method table.

There is only a slight increase in the ampicillin content (s) of each of the brands. This slight increase may be due to selective nature of spectrophotometric method carried out at specified wavelength of 322 mm. This slight increase may be also attributed to non-interference of the excipients used in the capsules formulations at 322 nm.

The two methods of analyses used in this study reveled that the two brands of ampicillin capsules miracillin and polfa are completely out of therefore specified for ampicillin capsules. Therefore, these two brands of ampicillin capsules are either take, substances and or adulterated.

The substandard nature of these two brands of ampicillin capsules has a significant heath implications for Nigeria and other West Africa Sub regions that depend on this drug market for their pharmaceutical supplied. The identification of this substandard brand of ampicillin capsules has serious effect of the chemical equivalence of this important sulphur containing brand spectrum antibiotics, its bioavailability and therapeutic drug potency. The use of some of these substandard, fake and or adulterated ampicillin capsules have been implicated in most Drug-diseases resistance cases currently ravaging the entire medical world, the least developing countries of Africa have been worst off. The prevalence of some of these substandard drugs has serious set back on the world health Millennium Development Goal (MDGs) come 2015.

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