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Research Article

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Chemical equivalence three brands of Aspirin sold in Sokoto State

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ABSTRACT

Chemical or Pharmaceutical equivalents are drug products that contain identical amounts of identical active ingredient. Two drugs with chemical equivalence does not imply bioequivalence. The aim of the work was to compare the the bioequivalents of three brands of Aspirin(A,B,C) obtained at differernt locations. Identification test, uniformity of weight test, assay test, disintegration test, friability test and hardness test were conducted on the selected brands using standard methods. In uniformity of weight test, brand A failed the test as five of its tablets deviated from the mean weight by more than 5% against two. Similarly, brands B and C failed the test completely as all tablets deviated.The three brands were however,found to contain aspirin as their active ingredient after conducting the verification test. After the assay test, brands A and B failed with percentage drug contents of 117.130% and 127.942% respectively. Only brand C passed the test giving a 102.714% content of aspirin.Brands B and C disintegrated after an average time of 0.40 minutes and 0.17 minutes respectively. Brand A gave an ambiguous 20.79 minutes against 20 minutes,therefore, failed the disintegration test. Brands A and C complied with the Standard of not more than 1% friability. Brand B failed the friability test, having showed a 7.67%. Hence brands A and B failed assay test for percentage content. Therefore, this research shows that the three brands are not pharmaceutically or chemically equivalent.

Key words: Asprin, Equivalence, Sokoto

INTRODUCTION

Chemical or Pharmaceutical equivalents are drug products that contain identical amounts of identical active ingredient. Two drugs' with chemical equivalence does not imply bioequivalence [1]. A tablet is a pharmaceutical dosage form. It comprises a mixture of *active substances* and excipients usually in powdered form, pressed or compacted from a powder into a solid dose. The excipients can include diluents, binders or granulating agents, glidants (flow aids) and lubricants to ensure efficient tableting; *disintegrants* to promote tablet-break-up in the digestive track; sweeteners or flavours to enhance taste; and pigments to make the tablets virtually attractive. A polymer coating is often applied to make the tablet smother and easier to swallow, to control the release rate of the active ingredient to make it more resistant to environment (extending its shelf life), or to enhance the tablet's appearance [2].

Quality Control (QC): It is a system of routine technical activities to measure and control the quality of the inventory as it is being developed. The quality control system is designed to; provide routine and consistent checks to ensure data integrity, correctness and completeness; identify and address errors and omissions. To achieve quality control, documentations and archive inventory materials and records of all quality control activities which include accuracy

checks on data acquisition and calculation, the use of approved standardized procedures, calculations, measurements and estimating uncertainties.

The aim is to compare the chemical equivelence of brands A, B, C of Aspirin and this will be achieve through the following objectives; uniformity test, identification test, assay test disintegration test, friability test and hardness test.

EXPERIMENTAL SECTION

Apart from other normal simple laboratory equipment/chemicals, the followings were used;

EQUIPMENT	MANUFACTURERS
Mosanto Hardness Tester	Guanglu, China
Disintegration Apparatus	Medicament Co. Ltd, China
Hardness Tester	Surginfield, China
Erweka Dissolution Apparatus	Erweka, Germany
Friabilator	Shangai Huanghai medicine testing instrument, Co. ltd
Water Bath	Memert, W. Germany
Weighing Balance (Electrical)	Ohause, China

Sampling method
The three different brands of aspirin tablets were obtained in August, 2011 from different parts of Sokoto state: Bodinga (Sokoto South), Kware (Sokoto North) and Gwadabawa (Sokoto East).

Uniformity Test
Twenty (20) tablets of each brand of the Aspirin were weighed separately and their individual weights were noted. The average weight was then calculated per brand of the drug.

According to official method [3], not more than two of the individual weights should deviate from the average weight by more than 5% and none should deviate by more than 10% from the average weight.

Disintegration Test
For each brand, a tablet was introduced in each of the six chambers of the apparatus. The assembly was suspended in a beaker containing water maintained at 37 ± 0.5°C , after operating it for 15 minutes, the assembly was removed from the water in the beaker.

The official method [3] states that the tablets pass disintegration test if all six tablets disintegrate within 15 minutes for uncoated tablets like aspirin tablets.

Friability Test
Loose dust was removed from both the drum and the sample using a soft brush. The total weight of the tablets were determined and placed in the drum of the friabilator. The drum was rotated at 25 rev/minutes for 4 mintes. Thereafter, the tablets were removed and loose dust removed again. The final weight of the 10 tablets were determined[3].

Identification Test
A quantity (500mg) of the powdered tablets was boiled with 10ml of 5M sodium hydroxide for 2 to 3 minutes. The solution was cooled and an excess of 1M sulphuric acid added. From the precipitate produced, a solution of it was made in water and small amoount of Iron (iii) Chloride added. This identification was done for all three (3) brands[3].

Assay Test
To 0.5grams of aspirin (500mg), 30ml of 0.5M 0f sodium hydroxide was added, boiled for 10 minutes and titrated with 0.5M hydrochloric acid using phenol red as indicator.

A blind titration was conducted using the same reagents. The differences between the titrations represented the amount of sodium hydroxide required.

According to the official method, each 1ml of 0.5M sodium hydroxide is equivalent to 45.04mg of Aspirin.

Hardness Test
Each tablet was placed between the jaws of the Mosanto hardness tester. The orientation of the tablets was in the same way with respect to the direction of the force applied. The force required to crush each tablet was noted in kgF. For each of the three brands, Six (6) tablets were employed for the Hardness test.

RESULTS AND DISCUSSION

Table 1 Result For Uniformity Of Weight Test

Brand	Mean uniformity of weight(mg)±STD	>5% deviation from mean weight	>10% deviation from mean weight	Remark
A	342±13	5	NIL	Failed
B	395±19	6	1	Failed
C	317±11	3	NIL	Failed

According to official method[3], not more than two tablets should deviate from the mean weight by 5% and not one should deviate by 10%

Table 2 Result For Disintegration Test

Brand	Mean time(min) (n=6)	Remark
A	20.79	Failed
B	0.40	Passed
C	0.17	Passed

The average disintegration time for all the three brands of Aspirin tablets is as stated below:
n= number of tablets used for the test

Less than or equal to 15 minutes is the acceptable disintegration time for uncoated tablets [3].

Table 3 Result For Friability Test

Brand	Intial weight (g)	Final weight (g)	Weight Loss (g)	% Loss	Remark
A	3.35	3.34	0.01	0.30	Passed
B	4.07	3.78	0.29	7.67	Failed
C	3.19	3.18	0.01	0.32	Passed

According to the offical method requirement, if no tablet is cracked, split or broken, the maximum loss of 1% of the tablet is considered to be acceptable.

Result For Identification Test
A Violet colour was produced in all the three brands, indicating the presence of aspirin.

Table 4 Result For Assay Test

Brand	% Content of Aspirin	Remark
A	117.13	Failed
B	127.94	Failed
C	102.71	Passed

Acceptable limit for assay test ;95-105

Table 5 Result For Hardness Test

Brand	Mean hardness ±SD n=6 (kgF)	Remark
A	6.4 ±0.3	Passed
B	4.0 ±1.3	Passed
C	4.6 ±0.8	Passed

Acceptable limit of hardness; 4 – 15 kgF

DISCUSSION

In uniformity of weight test, brand A failed as five (5) of its tablets deviated from the mean weight by more than 5%. This is contrary to the prescribed standard in the offical method of not more than two (2) tablets deviate from the mean weight by 5%. Similarly, brands B and C failed the tests.

Weight variation test is used to ensure that every tablet contains the specified amount of substances/ active principle with little variation among tablets in a batch. Factors that could affect uniformity of weight includes;

-Inconsistency of granule size
-Uneven filling of die cavity during compression of tablets.

Variation of active ingredients as a result of poor weight uniformity in a batch may lead to serious pharmacokinetic anomalies; toxicity and ineffectiveness of drug[4] . The three brands were found to contain aspirin as their active ingredient after conducting the verification test. The presence of aspirin in these tablets and in the correct amount, normal dose of the drug would show therapeutic efficacy.

As stated by the official method, percentage content of aspirin must fall within 95%-105%.

However after the assay test, brands A and B failed with percentage contents of 117.130% and 127.942% respectively. Only brand C passed the test, giving a 102.714 % content of aspirin. The assay test is critical test of quality. Good physical properties (taste, texture, or colour) would not matter if the content of active ingredient is below the standard[5]. A normal dose of low content product may lead to treatment failure or have an implication on the pharmacoeconomics of therapy. On the other hand, a normal dose of high content may pose other health problems[6]. Brands B and C disintegrated after an average of 0.40 minutes and 0.17 minutes respectively conforming with the B.P standard of not greater than 15 minutes. Brand A gave an ambiguous 20.79 minutes. Conclusively, only brand A failed the disintegration test. For a drug to be fully available for absorption, the tablet must disintegrate: this is a prerequisite for its discharge to body fluid[7].

Brands A and C complied with the BP standard of not more than 1% friability. Brand B failed the friability test, having showed a 7.67% loss.

Brands A and C would be able to withstand abrasion during packaging without significant loss of tablet weight. This feature cannot be attributed to brand B.

The brands had the optimum hardness of between 4KgF and 15KgF. Brands A, B and C passed hardness test with a mean hardness of 6.4, 4.0, and 4.6 respectively. A translation of the hardness result would be expected in the tablet's resistant to capping, abrasion or breakage during storage, transportation and handling.

CONCLUSION

The conditions for chemical equivalence are identical active ingredient, identical dosage form, route of administration and identical strength or concentration. And all the three brands passed these conditions except the identical strenth test. Hence brands A and B failed the assay tests for percentage content, it can be concluded that the brands are not pharmaceutically or chemically equivalent.

Recommendatoin
The study recommends that the evaluation of drug products from the stage of manufacturing through distribution to the point of consumption be taken seriously by drug regulatory bodies like National Agency for Food and Drug Administration (NAFDAC).

The study also recommends that manufacturers of Brand A and B comply with Good Manufacturing Practice (GMP) guidelines to ensure product efficacy.

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