Nigerian Journal of Pharmaceutical Sciences
Vol. 10, No. 1, March, 2011, ISSN: 0189-823X

CHEMICAL EQUIVALENCE STUDIES OF THREE BRANDS OF ASPIRIN TABLETS

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ABSTRACT

Three brands of Aspirin were analyzed for chemical equivalence studies. The biopharmaceutical parameters considered are Uniformity of Weight, identification, assay, disintegration, friability, hardness, and dissolution tests using B.P 2002 specification. Brands 02 and 03 complied to the B.P specification for the Weight Uniformity test. Brand 01 did not meet the B.P standard for the Weight Uniformity test. The values for the % content using the back titration procedure as specified by the B.P 2002 showed that Brands 01 and 02 had 118.004% and 127.01% respectively hence both Brands did not comply with the specified B.P standard of 95%-105%. Only Brand 03 passed the Assay test with a 98.18% percentage content of Aspirin. Brands 01, 02 and 03 passed the disintegration test showing 9.11 minutes and 13.1 and 6.67 minutes respectively which comply with standard ≤15 minutes for uncoated tablets. Brand 02 failed the friability test with a result of 9.32% weight loss as compared to the 1% maximum weight loss specified in the B.P Monograph. Brands 01 and 03 met with this specification with 0.307% and 0.29% weight loss respectively. Brands 01, 02, and 03 gave 8KgF, 4KgF, and 4.5KgF respectively in response to the Crushing Strength Test. All the Brands passed the Hardness test which has a specification of 4-15KgF as standard. The values obtained for dissolution after 45 minutes for Brand 01=71.67%, Brand 02=62.5% and Brand 03=77.5%. The overall result showed that all the three brands are not chemically equivalent to each other since Brand 02 did not meet the official standard of 70% release.

Key Words: Chemical Equivalence, Aspirin, Assay, Dissolution, Friability

INTRODUCTION

Pharmaceutical equivalent or chemical equivalent is referred to as drug products that contain identical active ingredients, identical strengths, and identical dosage forms and route of administration. Quality control is a term used to describe all measures designed to ensure the output of uniform batches of drugs that conform to established specifications of identity, strength, purity, and other characteristics. (Olaniyi *et al*, 2000). Quality assurance is a wide range of concept that individually or collectively influences the quality of a product. It also includes sum of the organized arrangement with the objective that medicinal products are of required quality for their intended use. It is a totality of arrangement deliberately designed and intended to ensure that products will be consistent with the quality appropriated for their use.

Good Manufacturing Practice, commonly referred to as GMP, is the part of quality assurance, which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use as required by the marketing authorization. The official quality control tests for tablets specified by the British

Pharmacopeia are: Uniformity of content of active ingredient, Disintegration, Dissolution and Friability Tests.

MATERIALS AND METHODS

Three brands of Aspirin were obtained from a renowned Pharmacy in Zaria, Kaduna State.

Brand 01

Batch Number: 081206

Manufacturing Date: 10/2009

Expiry Date: 10/2012

NAFDAC Registration Number: 044102

Strength: 300mg

Brand 02

Batch Number: BC-63

Manufacturing Date: 09/2009

Expiry Date: 09/2012

NAFDAC Registration Number: 08-4213

Strength: 300mg

Brand 03

Manufactured: 08/2009

Expiry Date: 07/2012

Batch Number: 0811

NAFDAC Registration Number: 04-0173

Strength: 300mg

Reagents used include Sodium hydroxide pellets, Hydrochloric acid (concentrated), concentrated Sulphuric acid, Iron (III) chloride solution, Phenol Red Indicator 10ml and water and the Glass wares used are Beakers (25ml, 50ml, 100ml, 250ml), Burette (50ml) (Pyrex), Funnel (Pyrex), Test tubes (Pyrex), Pipette (1ml, 5ml), Thermometer, Test tube holder, Measuring cylinder, Stirring Rod and Conical flask.

Methods

Identification Test carried out 500mg of the powdered tablets was boiled with 10ml of 5M sodium hydroxide for 2 to 3minutes. The solution was cooled and an excess of 1M Sulphuric acid was added and Iron (III) Chloride was also added. The identification test was performed for all the three brands. For Weight Uniformity Test twenty tablets were randomly selected and weighed individually with the Metler electronic balance and their average weight was calculated. Percentage deviation from the average was then determined. Same was done for each brand. For Crushing Strength the Monsanto Hardness tester was employed for the hardness test. For each brand, six tablets were used. For the Friability Test. Ten tablets were randomly selected and placed in Erweka friabilator chamber set at 25 rev/minute for 4 minutes. In Disintegration Test all the six tablets are to disintegrate within ≤15minutes for uncoated tablets like Aspirin tablets. 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 C°±0.5°C for 15 mins. In dissolution Test One litre of 0.1N HCl (free from dissolved air) was introduced into the vessel of dissolution apparatus, which was maintained at 37°C ± 0.5°C. One tablet was placed in a dry dissolution basket and then lowered into the dissolution medium until it was gone half way in the medium. The apparatus was operated for 45 minutes, for each tablet with 10ml of the sample withdrawn and diluted to 100mls out of which 4ml was taken for UV spectrophotometric

determination. The absorbance was measured at 265nm. This was done for each brand.. For Assay according to the B.P 2002, each 1ml of 0.5M sodium hydroxide is equivalent to 45.04mg of Aspirin. Thus For each brand of Aspirin, 20 tablets were weighed. To a quantity containing 0.5grams of Aspirin (500mg), 30ml of 0.5M of sodium hydroxide was added, boiled for 10 minutes and titrated with 0.5M hydrochloric acid using phenol red as indicator. This procedure was repeated without the substance being examined. The differences between the titrations represented was used to determine the percentage content of aspirin in the tablets

RESULTS

Identification test was carried out for all the three brands of Aspirin tablets using the procedure stated in B.P 2002 and a Violet colour was produced for all the three brands indicating the presence of Aspirin.

Table 1: Summary of all the Results

Brand	Uniformity of Weight(mg) mean±S.D n=20	Friability % loss n = 10	Hardness test n = 6 (KgF)	Disintegration time (min) n = 6	Dissolution mean % release n = 6	Content of active ingredient % W/W n = 20
01	312 ± 14.71	0.307	8	9.11	71.67	118.04
02	342.5±6.28	9.32	4	13.1	62.5	127.01
03	340±7.07	0.29	4.5	6.67	77.5	98.18

Table 2: Assay according to B.P 2002 the percentage content of Aspirin must be within 95-105%

Brand	% drug content	Remarks
01	118.04	Fail
02	127.01	Fail
03	98.18	Passed

DISCUSSION

The three brands were found to contain Aspirin as their active ingredient after Identification test. The percentage content of Aspirin must fall within 95%-105%. However after the Assay, brands 01 and 02 failed with percentage contents of 118.004% and 127.01% respectively. Only brand 03 passed the test, giving 98.18% .Brands 01, 02 and 03 disintegrated after an average of 9.6 13.1 and 6.67minutes respectively which is in accordance with BP standard of ≤ 15 minutes. For hardness test between 4KgF to 15KgF. Brands 01, 02 and 03 showed mean hardness of 8, 4 and 4.5 respectively. A translation of the hardness test result would be expected in the tablets' resistance to capping, abrasion or breakage during storage, transportation and handling. For dissolution test, only Brand 02 failed the dissolution test, showing 62.5% release as compared to the BP standard of a minimum 70% release. Brands 01 and 03 was77.5% and 71.67% respectively.

CONCLUSION

All the three brands passed the identification test but brands 01 and 02 failed the assay for percentage content; therefore all the brands are not pharmaceutically or chemically equivalent.

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