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Research Article

ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES OF METRONIDAZOLE TABLETS MARKETED IN ZARIA, NIGERIA

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ABSTRACT

Metronidazole is an antiparasitc agent used in the treatment of amoebiasis and other microbial diseases. It is an essential drug commonly sold in Nigerian Market. There are many different brands and dosage forms under various trade names by different pharmaceutical companies. In this study fifteen 15 brands/samples of metronidazole tablets marketed in pharmacy shops, hospitals and patent medicine vendor shops were randomly selected from different areas of Zaria. Label on the packages claims that all the samples contained 200mg of metronidazole per tablet. Some of the samples were manufactured in Nigeria while others were imported. All the samples examined were within their shelf life. The samples were subjected to official quality control tests such as active content uniformity, weight uniformity, disintegration and dissolution rate tests. The unofficial tests conducted included crushing strength/hardness, friability, and tablet thickness tests. All the brands passed the uniformity of weight, disintegration test, potency, dissolution and chemical identification tests. Six brands passed the crushing strength/hardness test, while two brands failed the friability test, The results indicate that only 60% of the sampled drugs passed the quality control tests.

Keywords: Assessment, Quality, Metronidazole Tablets, Zaria.

INTRODUCTION

Metronodazole is an antiprotozoal, anti parasitic agent, very effective in the treatment of amoebiasis, trichomoniasis, giardiasis and many other parasitic diseases. It occurs as pale-yellow crystals that is slightly soluble in water and alcohol [1].

There are many brands of metronidazole in the Nigerian market from different manufacturers. Some are manufactured locally and some imported. There are reliable evidence that some of them are fake, adulterated or substandard [2].

The calamities of fake and substandard drugs have caused a lot of health hazards to Nigerians and the necessity of controlling and preventing such practice is very necessary if we are to achieve health for all in Nigeria [3] and will greatly reduce Government spending on health due to disease and illnesses generated from the use of fake and substandard drugs and medicines.

In this study attempt was made to investigate and assess the pharmaceutical quality of different brands of metronidazole 200mg tablets marketed in Zaria town in order to ascertain the quality of the products.

MATERIALS AND METHODS

Metronidazole 200mg tablets were randomly purchased from pharmacies, hospitals and patents medicine vendors shops in Zaria town. Fifteen 15 samples from different manufacturers, all of the samples were labelled to contain 200mg metronodazole per tablets. All the tablets were plain compressed and uncoated. Reagents and chemicals utilized were of analytical grade, water used in this work was double distilled, standard procedures were used in all the analysis. Samples were stored as they were obtained and in the conditions specified by the manufacturers prior to their essay. The samples were collected between 20th January to 20th February 2006 from seven 7 areas of Zaria namely: Samaru, Hanwa, Shika, Sabon – Gari, Tudun Wada, Tudun Jukun and Zaria City.

The identity and specification of the various samples collected in the study is listed in Table 1.

Table 1: Shows the different brands on of metronidazole 200mg tablets randomly picked as samples

Code Number	Country of Origin	Manufacturing Date	Expiry Date
D	India	02/2005	03/09
E	Nigeria	10/2005	04/08
F	China	05/2005	05/09
G	Nigeria	01/2006	01/10
H	Nigeria	09/2003	08/07
J	Nigeria	11/2005	1/05
K	India	11/2004	10/07
L	Nigeria	01/2006	06/09
M	Nigeria	07/2005	07/09
N	India	03/2005	02/08
P	Nigeria	03/2006	03/2011
Q	Nigeria	02/2006	01/2011
R	Nigeria	02/2006	02/2009
S	Nigeria	02/2006	02/2009
T	Nigeria	03.2005	20/2009

The following important quality control tests were conducted on the tablets as per BP 1993 and 2002.

Disintegration time test

Disintegration rate test for six tablets selected at random from each container were determined using a disintegration rate test unit Erweka disintegration machine Germany, in O.N HCl solution maintained at 37 $\pm 1^0$C. One tablet was placed in one basket / unit of the medicine.

The individual time taken for all the tablet particles in each unit to pass through the mesh was recorded. Average of the time for the six tablets was taken as the disintegration time as shown in Table IV.

The dissolution time test

The dissolution rates of the active content from the tablets were determined using Erweka dissolution apparatus Germany. The dissolution medium was 0.1NHCl at 37± 0.5^{0}C. The paddles were caused to rotate at a rotational speed of 100rpm. Samples of 2ml were withdrawn after thirty minutes 30 minutes. The amount of metronidazole that had dissolved after 30 minutes was determined spectrophotometrically at 270nm using a digital UV Spectrophotometer 640SGV Jenway. The 2ml volume was replaced immediately with equal volume of 0.1HCl solution in a syringe in order to keep the volume of the association medium constant during the process of the test. All measurements were conducted in triplicate.

Crushing strength test

Twenty tablets randomly selected from each sample batch were used for this test. The crushing strength of each tablet was determined with mosonto hardness tester manesty machines Ltd. England Table IV.

Tablet friability, weight uniformity, thickness and tablet diameter tests were conducted on the samples using standard method [6] Table III.

Chemical identification test and content of active ingredient uniformity test were conducted according to the standard method in British Pharmacopea 2002 [7].

Table 2: Result of aesthetics tests carried out on the tablets

Sample	Colour	Shape	Lustre	Nature of surface Smooth or rough
D	Yellow	Circular flat surface tablets	Shiny	Smooth
E	Yellow	Circular convex surface tablets	Shiny	Rough edges
F	Yellow	Circular flat surface tablets	Dull	Smooth
G	Yellow	Circular flat surface tablets	Shiny	Few scratches on the surfaces
H	Yellow	Circular flat surface tablets	Dull	Smooth with rough edges
J	Yellow	Circular flat surface tablets	Shiny	Smooth
K	Yellow	Circular flat surface tablets	Shiny	Smooth
L	Yellow	Circular flat surface tablets	Shiny	Smooth
M	Yellow	Circular flat surface tablets	Dull	Smooth
N	Yellow	Circular convex surface tablets	Shiny	Smooth
P	Yellow	Circular convex surface tablets	Slightly shiny	Smooth with rough edges.
Q	Yellow	Circular flat surface tablets	Dull	Fairly smooth with rough edges.
R	Yellow	Circular flat surface tablets	Shiny	Smooth
S	Yellow	Circular Convex surface tablets	Dull	Smooth
T	Yellow	Circular Convex surface tablets	Dull	Smooth

Table 3: Results of unofficial quality control tests conducted on the metronidazole tablets

Code	Friability %	Crushing Strengh Kgf/kp	Tablet mean thickness mm	Tablet mean Diameter mm
D	0.59	6.50	3.83	12.90
E	0.98	7.75	4.24	11.50
F	1.31	5.10	3.54	11.0
G	9.66	3.70	3.91	11.50
H	0.52	4.85	3.68	12.50
J	0.19	9.73	3.63	14.00
K	0.85	12.95	3.96	12.00
L	0.34	8.73	3.63	12.50
M	0.18	5.08	3.94	14.00
N	0.15	10.08	4.33	12.50
P	0.42	5.53	4.34	12.00
Q	0.18	9.03	4.81	12.00
R	0.19	12.30	3.26	13.00
S	0.18	2.83	3.60	11.00
T	4.06	5.00	3.36	13.00

Table 4: Results of official quality control tests conducted on the metronidazole Tablets

Code	Mean Weight g	Disintegration Time Min	Dissolution Time after 30 Min %	Active Content uniformity test %
D	0.679 0.008	0.53	95.66	99.34
E	0.599 0.025	0.71	95.72	97.98
F	0.514 0.006	0.92	100.00	102.10
G	0.551 0.025	0.39	95.22	101.00
H	0.561 0.015	2.10	95.16	9.85
J	0.514 0.011	1.59	96.00	97.39
K	0.574 0.006	3.53	95.72	98.14
L	0.577 0.017	0.52	95.72	98.50
M	0.549 0.017	4.26	98.10	103.15
N	0.671 0.013	0.32	95.77	99.19
P	0.492 0.019	1.88	95.11	99.98
Q	0.540 0.012	1.04	95.16	98.14
R	0.5330.023	6.24	95.77	99.13
S	0.572 0.019	8.55	95.10	102.16
T	0.352 0.012	24.03	95.72	101.14

Standard deviation in parenthesis

RESULTS AND DISCUSSIONS

The results of aesthetics assessment of the tablets samples tested is listed in Table II. Most of the samples had good and impressive physical appearance except samples E, G, H, and Q that appeared to have rough edges with few scratches. Sample K was the most elegant of the samples. All samples were coloured yellow, might be due to pale yellow colour of metronidazole powder. As metronidazole occurs as a pale – yellow crystals. Tablets were circular in shape, some samples such as D, E, G, J, K, L, N and R were shiny lustre while others F, H, M, Q, S and T were dull in appearance.

From the results in Table III, for the unofficial tests conducted on the Metronidazole tablets, only six samples D,F,H,M,P, and T of Metronidazole tablets tested passed the test of crushing strength/hardness, the samples had acceptable crushing strength of between 4.85kgf to 6.50kgf. Sample R was the hardest of all the fifteen samples with a hardness of 12.30kgf, indicating that it was much above the limit range of between 4 to 7kgf stated.

The result of tablet friability test as shown in Table III, shows that most of the tablet samples tested showed impressive friability values ranging from 0.18%w/w to 0.98%w/w except samples G, and T. with friability values of 9.66 and 4.06%w/w. The two samples G and T have failed the friability test, as according to the limit, no compressed tablets batch should have a friability value of greater than 1.0%w/w, because only conventionally compressed tablets that lose less than 0.5 to 1.0% weight are generally acceptable. However, when "capping" is observed during friability testing, the tablet product is rejected regardless of the percentage weight loss.

Table IV shows the results of the official tests conducted on all the samples of metronidazole 200mg tablets sample D to T. All the samples passed the British Pharmacopeia BP specifications for disintegration rate test. The disintegration rates ranged from 0.32 sample N to 24.03 minutes Sample T, indicating that all the disintegration times were within the BP. Official limit of 30 minutes[7]. Also, the samples passed the weight variation/weight uniformity test as specified in the B.P. The mean tablets sample weight varied from 0.352 samples T to 0.679 sample D. It was observed that all the samples passed the dissolution time and potency or active content tests as specified in the official standard of B.P [7]. The British pharmacopea specifies that the metronidazole tablets should have a potency of between 95.0% to 105.0% 100.0 + 5%.

CONCLUSION

From the results above, it can be inferred that the manufacturers of the products tested have observed official standards and have utilized high pharmaceutical technologies regarding the quality standard of their product. However the manufacturers of sample G and T failed to produce tablets with good friability and crushing strength /hardness values, such tablets were not of good mechanical strength and could not withstand the normal risks of handling and transportation. The manufacturers may well be advised to improve on the mechanical strength of their tablets as it will seriously reduce the risk of breakage of their tablet products as a result of transportation and handling to the consumers.

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