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Pharmaceutical Equivalent Study of Mefenamic Acid Formulation available in Karachi, Pakistan

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ABSTRACT

The aim of this study is to check Pharmaceutical Equivalents of different brands of Mefenamic Acid tablets available in Karachi, Pakistan. Two different brands of Mefenamic Acid tablets (500 mg) were investigated in the study. Four quality control (QC) parameters: weight variation, hardness test, friability test and disintegration test were carried out specified by BP/USP (British and United State Pharmacopoeia). The result of study revealed that all the parameters such as weight variation, hardness, disintegration, friability were in accordance with BP/USP.

Keywords: *Mefenamic Acid, weight variation, hardness, friability, disintegration,Quality Control (QC) Parameters , BP/USP , Pharmaceutical Equivalents*

INTRODUCTION

Mefenamic acid belongs to non-steroidal anti inflammatory drugs (NSAID).[1]It is used as antirheumatic, antipyretic analgesic, for the treatment of dental pain,headache, postpartum and postoperative pain, osteoarthritis and dysmenorrheal. [2] The therapeutic use of mefenamic acid and others results from their inhibitory action on both cyclooxygenase (COX) enzymes and subsequent interference with the arachidonic pathway metabolites. [3] The nonsterodialanit-inflammatory drug (NSAID), mefenamic acid [2-(2, 3-dimethylphenylamino)] benzoic acid rarely shows but sometimes serious idiosyncratic nephro andhepatotoxicity.[4] A proposed mechanism for the development of these toxicities suggests that MFA is metabolized to chemically-reactive metabolites that become covalently bound to tissue proteins leading to adverse immunological responses.[5]

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EXPERIMENTAL

Tablet specification

All parameter (weight variation, thickness, hardness, friability and disintegration) of different brands of Mefenamic Acid were carried out.

Weight variation test

Variation in weight was checked on A.N.D Electronic Balance FX-400. Weight variation between tablet with respect to dose and weigh tmust be within BP limits. For which 20 tablets of each brand is selected randomly. In-process uniformity of weight is a test parameter which ensures evenness of dosage units through compression. The percentage weight variation from average tablet weight was calculated. In order to pass weight variation test, the tablet should be within the limits of the percentage deviation allowed by BP. Upper and lower control limit for weight variation is calculated as per following formula:

Upper control limit: Mean+ 3x Standard Deviation

Lower control limit: Mean- 3x Standard Deviation

Hardness test

This test is conducted on 10 tablets of each brand to determine the strength of tablet when applied mechanical stress. A tablet must be hard enough to endure stress. Hardness of all the brands is checked on MH-1, Hardness Tester of Galvano Scientific. The hardness value of each tablet was evaluated and average value was calculated and compared.

Friability test

No. of tablets were calculated to perform Friability test of each brand of Mefenamic Acid by subjecting to a uniform tumbling motion for specified period of time i.e. 25 rotation/minute for 4 minutes in FB–1004 CURIO Company and the weight loss is determined. Friability test is done to check if a tablet abrades during transportation by taking initial and final weight and determining the weight loss.

Disintegration test

Disintegration Testing is one of the quality control test done to determine whether capsules or tablets are disintegrating within the approved time when placed in a fluid medium. Disintegration test for all brands s was done on CURRO MODEL NO DS-0702. A 900 ml beaker was filled with distilled water and temperature was maintained at 37°C} 2°C. From each brand, 6 tablets of each brand were selected randomly and placed into the basket rack assembly and connected to the disintegration apparatus. The disintegration time for each brand is compared with the Pharmacopoeial limit specified by BP.

Table 1. Weight of 20 tablets (randomly selected) of different brands

Tablets	Brand A	Brand B
1	0. 33	0.605
2	0. 48	0.600
3	0. 18	0.600
4	0. 43	0.610
5	0. 33	0.590
6	0. 88	0.608
7	0. 12	0.608
8	0. 55	0.594
9	0. 95	0.599
10	0. 29	0.614
11	0. 65	0.598
12	0. 77	0.600
13	0. 91	0.583
14	0. 64	0.589
15	0. 123	0.559
16	0. 36	0.595
17	0. 79	0.600
18	0. 89	0.609
19	0. 40	0.594
20	0. 18	0.615

Table 2: Statistical Weight Variations

Tablets	Average (Gm)	Standard deviation	Upper limit (X+3S)	Lower limit (X-3S)
Brand A	0.512	0.28	1.352	-0.328
Brand B	0.590	0.01	0.620	0.560

Table 3: Weight Variation Test

tablets	**Result (Gm)**	**BP/USP Specification**	**Deviation from BP/USP Specification**
Brand A	0.512	Deviation should be ±7.5%	Within specified limit
Brand B	0.590	Deviation should be ±7.5%	

Table 4: Hardness of 10 tablets from the optimised formulation.

S.NO	**Mefnac**	**Ponstan**
1	7.4	6.72
2	6.4	7.85
3	7.17	6.2
4	5.99	7.9
5	5.83	6.01
6	7.83	8.76
7	7.44	8.36
8	7.72	9.38
9	7.37	8.36
10	7.60	7.13

Table 5: Statistical Hardness Calculation

no. of tablets	**Average HARDNESS (Kg)**	**Standard deviation**	**Upper limit (X+3S)**	**Lower limit (X-3S)**
Brand A	7.075	0.72	9.235	4.915
Brand B	7.6601	1.12	11.02	4.3

Table 6: Friability Test

Tablets	**Friability (%)**	**BP/USP specification**	**Deviation from BP/ USP specification**
Brand A	0.8 %	Not more than 1%	Within the specified limit
Brand B	0.76		

Table 7:Disintegration Test

Tablet	Disintegration time (min)	Limits	Deviation from USP
Brand A	4.5	Not more than 30 min for uncoated tablets	PASS
Brand B	5.0		PASS

RESULT AND DISCUSSION

The purpose of this research work was to compare and evaluate the quality standards of commercially available two brands of Mefenamic Acid Tablet in Karachi, Pakistan.

Weight variation test of Mefenamic Acid tablets proved statistically that all the tablets were in accordance to the BP/USP requirements as shown in the table 1, 2 & 3. Hardness test of Mefenamic Acid tablets were found deviating from BP/USP limits. Both the brands of Mefenamic Acid failed the hardness test i.e. average hardness of both brands was found to be greater than 4kg. Data of hardness test is given in table 4&5. Friability of both brands of Mefenamic Acid tablets was less than 1%. Therefore it is in compliance with BP/USP standards. Its data is given in table 6. Disintegration time of both the brands of Mefenamic Acid is observed. Both the tablets disintegrated within 5 minutes which in under the USP limits i.e. 30 minutes for uncoated tablets. Data of disintegration test is shown in table 7.

CONCLUSION

Both the two brands of Mefenamic Acid were pharmaceutical equivalents. No difference was subsist in weight variation, hardness testing, friability testing and disintegration testing of tablets.

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