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COMPARATIVE *IN VITRO* EVALUATION OF COMMERCIAL ACECLOFENAC TABLETS

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ABSTRACT

Four brands (A, B, C and D) of aceclofenac tablets (100 mg) manufactured in India were evaluated for six *in vitro* parameters, both official and non-official, viz., uniformity of weight, hardness test, friability test, disintegration test, dissolution test and assay. All the products met the requirements as per general specifications of Indian pharmacopoeia for tablet formulation. Assay value lies within the limit of 90% to 110%. The study on dissolution profile revealed that product **A** had faster dissolution rate while product C has slowest dissolution rate. This sort of study is good indicator for the *in vitro* evaluation of the idealness of commercial products. The obtained data may be useful for further formulation development studies.

Key words: Aceclofenac, Evaluation, Dissolution rate.

INTRODUCTION

Aceclofenac (ACL), chemically [0, (2, 6-dichloraoanilino phenyl) acetate glycolic acid ester, is a synthetic new NSAID, which has been widely used in treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis with minimum side effects. ACL tablet is not an official product of I. P. ACL and it is practically insoluble in water. Therefore, it may gives rise to dissolution related absorption problem. Since ACL tablet is an unofficial product and practically insoluble in water, it was thought necessary to carryout *in vitro* testing of the commercial products with special attention to dissolution rate studies. Tablets of 100 mg were chosen for the investigation.

Quality of pharmaceutical product is the most important for efficacy and safety of product. Quality of product refers to its confining to the standards pre-set to assure the desired purpose. There are more than 15 commercial ACL tablets available in Indian

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market. Even though they contain identical active ingredients, additives (which are not disclosed on label), the process of manufacturing may however differ. The present study has been undertaken to evaluate various quality control parameters along with *in vitro* dissolution profile of four available marketed ACL tablets and results are reported here.

EXPERIMENTAL

Materials

Aceclofenac 100 mg tablets of 4 different brands were purchased. All the products were manufactured within six months from the date of study. ACL pure drug was supplied by ARSVIL RESEARCH LAB Pvt Ltd. Vijayawada and all other chemicals used were of analytical grade. The products were coded as A, B, C and D. The labeled self life of all products was 36 months. The product was evaluated for uniformity of weight, hardness test, friability test, disintegration test, dissolution test and assay.

Methods

Uniformity of weight

The test was carried out on 20 tablets as per specified in I. P. Average weight and maximum percentage deviation were determined.

Hardness test

The hardness test was done for five tablets using Monsanto hardness tester. The average value was recorded.

Friability test

This test was performed on 20 tablets using Roche friabilator. The dedusted tablets were weighed and put in the friabilator, after 100 revolutions, the tablets were dedusted and weighed. Percent loss in weight was recorded.

Disintegration test

The test was carried out on six tablets using I. P. apparatus with disc in distilled water medium at $37^{o}C \pm 1^{o}C$. The average D. T. was recorded.

Dissolution test

Dissolution rate of ACL from tablet was studied using USP XXI dissolution test apparatus. The quantity of dissolution medium was 900 mL of phosphate buffer pH 6.8,

with the speed of rotation at 100 rpm and the temperature was set at 37 ± 0.5ºC. The sample were withdrawn at 5 minute internal. The withdrawn samples were suitably diluted with more quantity of dissolution medium and the same volume was replaced with fresh dissolution medium. The samples were then studied in UV spectrophotometer at 273 nm for ACL content. The release rate at various time internals were then determined.

Assay

Ten tablets from each brand were taken; powdered well and a quantity of powder equivalent to 50 mg of ACL was taken assay. The assay was carried at as per the method reported by Shanmugam[3] for ACL tablet. The assay results was expressed as percent of labeled amount of ACL.

RESULTS AND DISCUSSION

As per I. P., the tablets weighing more than 80 mg but less than 250 mg can have the deviation of maximum 7.5%. All the brands of tablets were within that range particularly the brand A was only 1.82%. Using Monsanto hardness tester, the strength of the tablets were tested. All the tablets showed good strength, which is necessary for safe transportation. Sample D had minimum hardness while B and C have maximum hardness. The friability was carried out for all the brands of tablets. The friability was less than 0.1% for all the brands. The values of less then 1% are considered to be highly satisfactory evaluation characteristics. All the brands of tablets disintegrated before 15 minutes. It conformed to the I. P. specifications. The brand D disintegrated within 30 seconds. Assay value of all ACL tablets were within the range of 90% to 110% of stated amount of ACL. The dissolution test was carried at in 8 station USP XXI Dissolution apparatus under specified test condition.. The release of the drug was observed till 30 minutes. From the data, it was interesting to note that more than 80% drug released from brand D with in 15 min, while the product C release were around 45.5.%, product A released 60.30%; and B released was 62.47 %, This can also be attributed to the relationship between disintegration time and dissolution time of the products. The variation in the dissolution, the profile of this commercial ACL tablet was in the following descending order D> A > B > C.

CONCLUSION

All the products gave satisfactory results, in respect of uniformity of weight, hardness test, friability test assay and disintegration time, but higher variation in dissolution profiles of brand C, may be due to formulation and processing equipments of

the manufacturers.

REFERENCES

1. Pharmacopoeia of India, Vol 1, Ministry of Health and Family Welfare, Govt. of India, Controller of Publ., Delhi, (1996) p. 188.
2. Pharmacopoeia of India. Vol 11, Ministry of Health and Family Welfare, Govt. of India, Controller of Publ., Delhi, (1996) p. A-82.
3. S. Shanmugam, Indian Drugs, **42(2)**, 106 (2005).
4. British Pharmacopeia, Vol I., 33-34 (1998).
5. The Merck Index, Thirteenth Edition, p. 22

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