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IN VITRO DISSOLUTION STUDIES OF SOME COMMERCIAL BRANDS OF ACECLOFENAC TABLETS

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ABSTRACT

Aceclofenac has higher anti-inflammatory action than conventional NSAIDs. It is used for the relief of pain and inflammation in rheumatoid arthritis, osteoarthritis and ankylosing spondylitis with minimum side effects. Since Aceclofenac tablet is not an official product of I. P. and practically insoluble in water, it was thought to necessary to carryout in vitro testing of the commercial products with special attention to dissolution rate studies. The aim of the present study is to conduct the comparative dissolution studies to find out brand-to-brand variation by applying comparison approaches to the dissolution profile of marketed aceclofenac tablet formulations. Commercially available five different brands of aceclofenac tablets were randomly sampled from different medical shops. The study protocol was designed as per Indian Pharmacopeia. All the products met the requirements as per general specifications of Indian pharmacopoeia for tablet formulation.

KEYWORDS: Aceclofenac, Indian Pharmacopeia, Dissolution, Commercial, Tablet formulation.

INTRODUCTION

Aceclofenac ([[[2-[(2, 6-Dichlorophenyl) amino] phenyl] acetyl] oxy] acetic acid) is a non-steroidal anti-inflammatory drug (NSAID) analog of Diclofenac. It is used for the relief of pain and inflammation in rheumatoid arthritis, osteoarthritis and ankylosing spondylitis with minimum side effects. The dose is 100 mg twice daily. It is a cytokine inhibitor. Aceclofenac works by blocking the action of a substance in the body called cyclo-oxygenase. Cyclo-oxygenase is involved in the production of prostaglandins (chemicals in the body) which cause pain, swelling and inflammation. Aceclofenac is the glycolic acid ester of diclofenac.[1,2] To assess the standard of a product, in vitro dissolution test is widely used

because, for any solid dosage forms, gastrointestinal absorption first requires dissolution of the tablet or capsule that liberates the drug into solution.[3] The dissolution characteristic of a drug from the dosage form depends on many factors including its formulation and manufacturing process.[4] The main objective of the study deals with the comparative in vitro dissolution characteristics of commonly available five brands of Aceclofenac tablet in order to find out any out of compliance market preparation.

Since Aceclofenac tablet is not an official product of I. P. and practically insoluble in water, it was thought necessary to carryout in vitro dissolution testing of the commercial products with special attention to dissolution rate studies.

MATERIALS AND METHODS

Materials: Different brands of Aceclofenac 100mg tablets were manufactured by different companies were randomly purchased from different medical shops and coded as A, B, C, D and E. All Aceclofenac tablets were of same manufacturing year and were recently manufactured.

Dissolution studies: Dissolution was performed on five formulations of 100 mg aceclofenac tablets coded as A, B, C, D and E formulations. Dissolution was carried out using USP apparatus-II (Paddle) at 37ºC ± 0.5ºC in 900 ml phosphate buffer medium of pH 6.8 at 50 rpm. After appropriate time interval, a sufficient volume of sample was withdrawn and filtered through Whatman filter No. 41. Immediately, same volume of the fresh dissolution medium was transferred to the dissolution flask. Samples were collected at suitable time interval and analyzed spectrophotometrically at 275 nm.[5]

RESULTS AND DISCUSSION

A dissolution study gives an idea of the amount of drug available for absorption after oral administration. Drugs with poor dissolution profiles will not be available in the body system or target organs/tissues to elicit therapeutic effect. The comparative in vitro dissolution profiles of various commercially available Aceclofenac 100mg tablets are shown in Figure 1. The in vitro dissolution profiles were found to be varying for each brand-to-brand tablets but within the prescribed limit.

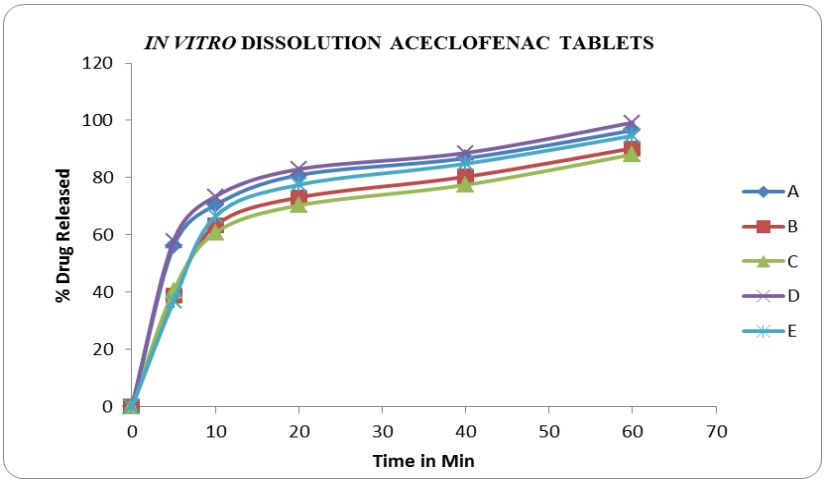

Figure. 1: In Vitro Dissolution Profile of Aceclofenac Tablets.

CONCLUSION

The branded tablets chosen in our study revealeved similar dissolution profiles in compliance with IP requirement of 80% of the drug dissolved within 15-20 mins, predicting in vivo bioequivalency.

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