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Comparative in vitro dissolution study of Aceclofenac Marketed Tablets in Two Different Dissolution Media by Validated Analytical Method

S.M. Ashrafur Islam, Sharmi Islam, Mohammad Shahriar and Irin Dewan

ABSTRACT

In this study five marketed brands of aceclofenac 100 mg tablets have been evaluated using dissolution test in two different media with the aim to assess bioequivalence and to select a proper dissolution medium. Other general quality parameters of these tablets like weight variation, hardness, friability, disintegration time were also determined according to established protocols. All the brands complied with the official specification for friability, uniformity of weight, disintegration time and drug content. UV spectroscopic and RP-HPLC methods were validated for the parameters like linearity, accuracy, precision and robustness. Potency was determined by using these two methods. Potency obtained from UV method and HPLC methods were found similar with paired *t* test. Dissolution test results were subjected to further analysis by difference factor (D1), similarity factor (D2) and dissolution efficiency (% DE). Higher drug release was found in phosphate buffer pH 6.8 than in 0.05% sodium lauryl sulphate solution. All brands were found similar in respect of drug release in phosphate buffer pH 6.8 but they differ in respect of drug release in 0.5% sodium lauryl sulphate. So phosphate buffer pH 6.8 may be a suitable media for dissolution study of aceclofenac tablets.

Keywords: Aceclofenac, method validation, similarity factor (D2), dissolution efficiency (% DE), dissolution comparison.

INTRODUCTION

The main purpose of solid dosage form is to make a drug available to the human body at a certain rate and define amount through the gastro intestinal tract so that the drug can produce pharmacological effects. But studies on bioavailability of drugs from a given dosage form revealed that, in many situations, solid dosage forms did not give the same therapeutic effects. This is mainly due to the insufficient dissolution and subsequent absorption of the drug from the GIT. So, dissolution analysis of pharmaceutical solid dosage forms is a very important test of product quality (Hsu et al., 1989). Aceclofenac, [(2-[(2,6-dichlorophenyl)amino] phenyl)acetoxyacetic acid] is a non-steroidal anti-inflammatory drug (NSAID) indicated for the symptomatic treatment of pain and inflammation with a reduced side effect profile, especially gastro-intestinal events that are frequently experienced with NSAID therapy. Aceclofenac is practically insoluble in water with good permeability (calculated log P = 2.170) and belongs to biopharmaceutics classification system (BCS) class II (low solubility, high permeability). Therefore, AC shows dissolution rate limited absorption that gives rise to difficulties in pharmaceutical formulations for oral delivery, which may lead to variable bioavailability. Therefore constant surveillance on marketed aceclofenac tablets by the government, manufactures and independent research groups is essential

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Comparative In Vitro Dissolution Study Of Aceclofenac

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Polysaccharide Carriers for Drug Delivery Sabyasachi Maiti,Sougata Jana,2019-06-14 Polysaccharide Carriers for Drug Delivery presents the latest information on the selection of safe materials Due to reported safety profiles on polysaccharides they have been the natural choice for investigation A wide variety of drug delivery and biomedical systems have been studied however the related information either concept wise or application oriented is scattered therefore becoming difficult for readers and researchers to digest in a concise manner This gathering of information will help readers easily comprehend the subject matter Focuses on biopolysaccharide based distinct approaches for drug delivery applications Illustrates new concepts and highlights future scope for clinical development Provides comprehensive up to date information on different aspects of drug delivery technology

Solid Dispersion of Aceclofenac and B-Cyclodextrin Complex Khushal Dhamat,Nirmal Shah,Chirag Bhalala,2012-07 Aceclofenac is an effective analgesic and anti inflammatory drug prescribed widely in recent years for various types of pain and inflammation Aceclofenac is partially insoluble in water and aqueous fluid and as such it exhibits poor variable oral bioavailability Aceclofenac needs enhancement of solubility and dissolution rate to improve its oral bioavailability and therapeutic efficacy Among the various approaches to enhance the solubility and dissolution rate of poorly soluble drugs complexation with cyclodextrin is an effective and industrially accepted technique In the present investigation Complexation of aceclofenac with CD was carried out by using various techniques like physical mixture kneading method co precipitate method solvent evaporation method From the various characterization studies like drug content production yield in vitro dissolution study Data were further treated with statical analysis using ANNOVA model and from the result of statical analysis batch abc 6 by kneading method was selected as optimised batch Optimised batch was also studied for FTIR and DSC studies

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