



ISSN: 2231-3354
Received on: 06-11-2011
Revised on: 17-11-2011
Accepted on: 26-11-2011

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

S.M. Ashrafur Islam, Sharmi Islam,
Mohammad Shahriar and Irin Dewan
Department of Pharmacy, University
of Asia Pacific, Dharmadi,
Dhaka-1209, Bangladesh

For Correspondence
S.M. Ashrafur Islam
Department of Pharmacy,
University of Asia Pacific,
Dharmadi, Dhaka-1209,
Bangladesh.
Tel: +880-2-9664953, Fax: +880-2-9664950,
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G Psacharopoulos



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