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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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Nanobiomaterials Thandapani Gomathi, P.N. Sudha, Sabu Thomas, 2023-10-13 Nanobiomaterials Research Trends and Applications Biomaterials are derived from natural resources such as plants animals and marine sources These biomaterials have advanced applications across a range of key industries due to their low cost being easy to process being biocompatible and so on The modification of biomaterials in the nanoform enhances their applications The book begins with an overview of nanobiomaterials processing classifications fabrication and sustainability In depth chapters in Part I address the most recent methods and techniques for physicochemical characterisation processing of blends and composites based on nanomaterials and separation Chapters in Part II focus on the biological and biomedical applications specifically in antimicrobial chemotherapy drug delivery tissue engineering cancer therapeutics robust biosolar cells and 3D printing The chapters in Part III mostly focus on environmental applications including wastewater treatment water desalination bioremediation and agricultural uses The book is extremely useful for scientists R D specialists designers and engineers across sectors and disciplines who are interested in using biopolymers for parts and products

Sustainable Approaches in Pharmaceutical Sciences Kamal Shah, Durgesh Nandini Chauhan, Nagendra Singh Chauhan, 2023-10-26 Highly comprehensive and detailed text on best possible sustainable approaches associated with the development design and origination of pharmaceuticals Sustainable Approaches in Pharmaceutical Sciences enables readers to understand the best possible green approaches associated with the development design and origination of pharmaceuticals including resources that may minimize the adverse effects associated with synthesis isolation and extraction Sustainable Approaches in Pharmaceutical Sciences covers a myriad of current topics including mechanochemical improvements for API synthesis as well as the role of artificial intelligence AI in the development and discovery of pharmaceuticals along with recent developments in hydrogels which respond to triggered factors during topical drug delivery Authored by experienced scientists from institutions across the world other sample topics covered in Sustainable Approaches in Pharmaceutical Sciences include Green technologies and benefits associated with them white biotechnology green chemistry and eco friendly approaches for designing active pharmaceutical ingredients Impact of

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Parambath,2018-02-01 Engineering of Biomaterials for Drug Delivery Systems Beyond Polyethylene Glycol examines the combined issues of PEGylation and viable biomaterials as alternatives With a strong focus on polymeric biomaterials the book first reviews the major issues associated with PEGylation and its use in vivo Chapters then focus on alternative polymer systems for drug delivery systems Finally nanoparticles and future perspectives are examined This book is a valuable resource for scientists and researchers in biomaterials pharmaceuticals and nanotechnology and all those who wish to broaden their knowledge in this field Provides a self contained work for the field of biomaterials for drug delivery Summarizes the current knowledge on PEGylation and strategies for bypassing it Presents research on an important though under represented issue in biomaterials Written by a world class team of research scientists engineers and clinicians

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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 statistical analysis using ANNOVA model and from the result of statistical 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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