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

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

ABSTRACT

In this study five marketed brands of accelestence 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 protecols. 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 (IT), similarity factor (IZ) 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 phosphate buffer pH 6.8 may be a suitable media for dissolution study of neecloclerac tablets.

Keywords: Aceclofenac, method validation, similarity factor (f2), dissolution efficiency (% DE), dissolution comparison,

INTRODUCTION

The main purpose of solid desage 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 desage form reveled that, in many situations, solid desage 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 desage forms is a very important test of product quality (Plsu et al., 1989). Aceclofenae, . [(2-(2.6-dichlorophenyllamino)] phenylacetooxyacetic 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. Aceclofenae 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 aceclofenae tablets by the government, manufactures and independent research groups is essential

S.M. Aohraful Islam, Sharmi Islam, Mohammad Shahrilar and Irin Dewan Dryantment of Pharmary, University of Asia Pacific Dhammonth, Dhata-1203, Bangladish

For Correspondence S.M. Adhraful Blam Department of Pharmacy, University of Asia Pacific, Disamondi, Dhaka-1200, Beneficials

TeC +880-2-9664953 Ext-136, Fax: + 88.02.9664950

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Emmanuel Scheubel

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Handbook of Composites from Renewable Materials, Polymeric Composites Vijay Kumar Thakur, Manju Kumari Thakur, Michael R. Kessler, 2017-03-16 This unique multidisciplinary 8 volume set focuses on the emerging issues concerning synthesis characterization design manufacturing and various other aspects of composite materials from renewable materials and provides a shared platform for both researcher and industry The Handbook of Composites from Renewable Materials comprises a set of 8 individual volumes that brings an interdisciplinary perspective to accomplish a more detailed understanding of the interplay between the synthesis structure characterization processing applications and performance of these advanced materials The Handbook comprises 169 chapters from world renowned experts covering a multitude of natural polymers reinforcement fillers and biodegradable materials Volume 6 is solely focused on the Polymeric Composites Some of the important topics include but not limited to Keratin as renewable material for developing polymer composites natural and synthetic matrices hydrogels in tissue engineering smart hydrogels application in bioethanol production principle renewable biopolymers application of hydrogel biocomposites for multiple drug delivery nontoxic holographic materials bioplasticizer epoxidized vegetable oils based poly lactic acid blends and nanocomposites preparation characterization and adsorption properties of poly DMAEA cross linked starch gel copolymer in wastewater treatments study of chitosan cross linking hydrogels for absorption of antifungal drugs using molecular modelling pharmaceutical delivery systems composed of chitosan eco friendly polymers for food packaging influence of surface modification on the thermal stability and percentage of crystallinity of natural abaca fiber influence of the use of natural fibers in composite materials assessed on a life cycle perspective plant polysaccharides blended ionotropically gelled alginate multiple unit systems for sustained drug release vegetable oil based polymer composites applications of chitosan derivatives in wastewater treatment novel lignin based materials as a products for various applications biopolymers from renewable resources and thermoplastic starch matrix as polymer units of multi component polymer systems for advanced applications chitosan composites preparation and applications in removing water pollutants and recent advancements in biopolymer composites for addressing environmental Handbook of Research on Nano-Drug Delivery and Tissue Engineering Rajakumari Rajendran, Hanna J Maria, Sabu issues Thomas, Nandakumar Kalarikkal, 2022-03-09 With contributions from leading researchers in the nanomedicine field from industry academia and government and private research institutions across the globe the volume provides an up to date report on topical issues in nano drug delivery and nanotechnological approaches to tissue engineering The volume offers research on a variety of diverse nano based drug delivery systems along with discussions of their efficacy safety toxicology and applications for different purposes Focusing on nanotechnology approaches to tissue engineering this volume considers the use of hydrogel systems nanoceria and micro and nano structured biomaterials for bone tissue engineering mesenchymal stem cells and more 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 sustainable approaches in pharmaceutical industries regarding use of solvents nanoparticles formulations and antimicrobial bandages Micro extractive methods capable of generating high recovery values of the analytes and associated techniques such as dispersive liquid liquid microextraction Benefits of the exploration of sustainable chemistry on a commercial scale particularly in relation to bioresources chemical manufacturing and organic transformation Discussing both the foundational science and practicality of different approaches regarding human and environmental health Sustainable Approaches in Pharmaceutical Sciences is an essential resource for scientists medical professionals and industrial professionals working in the fields of sustainable technology and synthesis in pharmaceutical sciences along with advanced level students The Pharmacist ,2007 Engineering of Biomaterials for Drug Delivery Systems Anilkumar 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 **Indian Science Abstracts** ,2012-03 SOUVENIR of 2nd International Science Congress (ISC-2012) Prof. Dipak Sharma, The International Science

Congress Association organized the 2nd International Science Congress ISC 2012 with Science and Technology Challenges of 21st Century as its focal theme ISC 2012 was divided in 20 sections A total number of 800 Research Papers and 1200 registrations from 23 countries all over the world have been received They was mainly from Bangladesh Bulgariya Cameroun

France Greece Iran Iraq Kazakhstan Korea Lithuania Malaysia Nigeria Nepal Phillipines Pakistan Poland Romania Slovakiya USA Ukraine Venezuela Turkey and India Gums, Resins and Latexes of Plant Origin Hosakatte Niranjana Murthy,2022-07-20 This reference book provides a comprehensive overview of natural gums resins and latexes of plants with a focus on their chemistry biological activities and practical uses The content is divided into five main sections each of which contains chapters contributed from valuable experts in their field Naturally occuring plant products have quite diverse applications in many different industries The book aims to highlight the important aspects of plant based gums resins and latexes as well as provide a strategic framework for further research and development activities on these bioproducts It will appeal to a broad audience such as biologists pharmacologists pharmacists food technologists and medical practitioners It is also a useful resource for research investigators of the healthcare industry academia and students of biomedical sciences

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 Predictive in Vitro Dissolution Tools Emmanuel Scheubel, 2010 Dissolution has emerged as a key method DSC studies during development of medicines and for quality control of marketed products At the early stage of development dissolution guides the selection of toxicology and first test in man formulations At later stages of development dissolution tests are performed to compare prototype formulations the robustness of the manufacturing process to indicate stability and to assure

safe release and reproductibility of the products to the market However despite they wide use in pharmaceutical development several challenges still exist In particular there is a lack of thorough identification and understanding of the critical quality attributes that control dissolution of Active Pharmaceutical Ingredient and Drug Product Dissolution exhibits clearly a higher predictability if it can be extrapolated directly to in vivo behavior Thepresent work focuses on the optimization of the existing and alternative dissolution techniques to lay a foundation for Quality by Design QbD principles In Vitro In Vivo Correlation IVIVC and In Vitro In Vivo Relationship IVIVR The dissolution applied on API and on differente formulations types Immediate release and extended release form during the different development phases as well as for generic has been explored Simple and cost effective dissolution methods were shown to be potential surrogate for in vivo performance and serve as well for strong quality control method. The future perspectives and central role of dissolution testing are presented and discussed Sodium Alginate Floating Pellet Of Aceclofenac Swati Paul, Dibyajyoti Saha, 2012 Accelofenac floating pellets where prepared by extrusion spheronization method and the drug released profile of accelofenac was investigated Different batches of pellets were prepared by using sodium alginate and HPMC K4M HPMC K100LV as polymer In vitro dissolution of pellets was carried out in USP apparatus XXIV paddle method at 50rpm The drug release was measured by using UV spectroscopy of max of 273nm for acid buffer media The dissolution data were treated with zero order first order and Higuchi model Half of the formulations were fitted to Higuchi model and to the first order model Finally it can be concluded that with the increasing polymer concentration to optimum level the release rate of Aceclofenac was satisfactory but further increased causes decreased of Aceclofenac release **Guidance for in Vivo Bioequivalence** Study and in Vitro Dissolution Testing on Metaproterenol Sulfate Tablets Wallace P. Adams, Center for Drug Evaluation and Research (U.S.). Division of Bioequivalence, 1986*

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