Design And Analysis Of Bioavailability And Bioequivalence Studies Third Edition Chapman Hallcrc Biostatistics Series

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Bioavailability Control by Drug Delivery System Design
Applied Biopharmaceutics and Pharmacokinetics
Analytical Similarity Assessment in Biosimilar Product Development

JOHNNY HUDSON

Generics and Bioequivalence Wiley-Interscience
To achieve and maintain optimal health, it is essential that the vitamins in foods are present in sufficient quantity and are in a form that the body can assimilate. Vitamins in Foods: Analysis, Bioavailability, and Stability presents the latest information about vitamins and their analysis, bioavailability, and stability in foods. The contents of the book is divided into two parts to facilitate accessibility and understanding. Part I, Properties of Vitamins, discusses the effects of food processing on vitamin retention, the physiology of vitamin absorption, and the physiochemical properties of individual vitamins. Factors affecting vitamin bioavailability are also discussed in detail. The second part, Analysis of Vitamins, describes the principles of analytical methods and provides detailed methods for depicting individual vitamins in foods. Analytical topics of particular interest include the identification of problems associated with quantitatively extracting vitamins from the food matrix; assay techniques, including immunoassays, protein binding, microbiological, and biosensor assays; the presentation of high-performance liquid chromatography (HPLC) methodology illustrated in tables accompanied by step-by-step details of sample preparation; the explanation of representative separations (chromatograms) taken from original research papers are reproduced together with ultraviolet and florescence spectra of vitamins; the appraisal of various analytical approaches that are currently employed. Comprehensive andcomplete, Vitamins in Foods: Analysis, Bioavailability, and Stability is a must have resource for those who need the latest information on analytical methodology and factors affecting vitamin bioavailability and retention in foods.
Drug Absorption and Disposition Springer
Absorption, Distribution, Metabolism and Excretion (ADME) processes and their relationship with the design of dosage forms and the success of pharmacotherapy form the basis of this upper level undergraduate/graduate textbook. As an introduction oriented to pharmacy students, it is also written for scientist from different fields outside of pharmaceutics. (e.g. material scientist, material engineers, medicinal chemists) who might be working in a positions in pharmaceutical companies or whose work

might benefit from basic training in the ADME concepts and some biological background. Pedagogical features such as objectives, keywords, discussion questions, summaries and case studies add valuable teaching tools. This book will provide not only general knowledge on ADME processes but also an updated insight on some hot topics such as drug transporters, multi-drug resistance related to pharmacokinetic phenomena, last generation pharmaceutical carriers (nanopharmaceuticals), in vitro and in vivo bioequivalence studies, biopharmaceuticals, pharmacogenomics, drug-drug and food-drug interactions, and in silico and in vitro prediction of ADME properties. In comparison with other similar textbooks, around half of the volume would be focused on the relationship between expanding scientific fields and ADME processes. Each of these burgeoning fields has a separate chapter in the second part of the volume, and was written with leading experts on the correspondent topic, including scientists and academics from USA and UK (Duquesne University School of Pharmacy, Indiana University School of Medicine, University of Utah College of Pharmacy, University of Maryland, University of Bath). Additionally, each of the initial chapters dealing with the generalities of drug absorption, distribution, metabolism and excretion would include relevant, classic examples related to each topic with appropriate illustrations (e.g. importance of active absorption of levodopa, implications in levodopa administration, drug drug interactions and food drug interactions emerging from the active uptake; intoxication with paracetamol as a result of glutathione depletion, CYP induction and its relationship with acute liver failure caused by paracetamol, etc). ADME Processes and Pharmaceutical Sciences is written as a core textbook for ADME processes, pharmacy, pharmacokinetics, drug delivery, biopharmaceutics, drug disposition, drug design and medicinal chemistry courses.

Statistics in Drug Research McGraw-Hill/Appleton & Lange

The peroral application (swallowing) of a medicine means that the body must first resorb the active substance before it can begin to take effect. The efficacy of drug uptake depends on the one hand on the chemical characteristics of the active substance, above all on its solubility and membrane permeability. On the other hand, it is determined by the organism's ability to absorb pharmaceuticals by way of specific transport proteins or to excrete them. Since many pharmacologically active substances are poorly suited for oral intake, a decisive criterion for the efficacy of a medicine is its so-called bioavailability. Written by an international team from academia and the pharmaceutical industry, this book covers all aspects of the oral bioavailability of medicines. The focus is placed on methods for determining the parameters relevant to bioavailability. These range from modern physicochemical techniques via biological studies in vitro and in vivo right up to computer-aided predictions. The authors specifically address possibilities for optimizing bioavailability

during the early screening stage for the active substance. Its clear structure and comprehensive coverage make this book equally suitable for researchers and lecturers in industry and teaching.

Design and Analysis of Clinical Trials CRC Press The US Food and Drug Administration's Report to the Nation in 2004 and 2005 indicated that one of the top reasons for drug recall was that stability data did not support existing expiration dates. Pharmaceutical companies conduct stability studies to characterize the degradation of drug products and to estimate drug shelf life. Illustrating how stability studies play an important role in drug safety and quality assurance, Statistical Design and Analysis of Stability Studies presents the principles and methodologies in the design and analysis of stability studies. After introducing the basic concepts of stability testing, the book focuses on short-term stability studies and reviews several methods for estimating drug expiration dating periods. It then compares some commonly employed study designs and discusses both fixed and random batch statistical analyses. Following a chapter on the statistical methods for stability analysis under a linear mixed effects model, the book examines stability analyses with discrete responses, multiple components, and frozen drug products. In addition, the author provides statistical methods for dissolution testing and explores current issues and recent developments in stability studies. To ensure the safety of consumers, professionals in the field must carry out stability studies to determine the reliability of drug products during their expiration period. This book provides the material necessary for you to perform stability designs and analyses in pharmaceutical research and development.

Bioequivalence and Statistics in Clinical Pharmacology CRC Press A unique, unifying treatment for statistics and science in clinical trials What sets this volume apart from the many books dealing with clinical trials is its integration of statistical and clinical disciplines. Stressing communication between biostatisticians and clinical scientists, this work clearly relates statistical interpretation to clinical issues arising in different stages of pharmaceutical research and development. Plus, the principles presented here are universal enough to be easily adapted in non-biopharmaceutical settings. Design and Analysis of Clinical Trials tackles concepts and methodologies. It not only covers statistical basics such as uncertainty and bias, design considerations such as patient selection, randomization, and the different types of clinical trials but also deals with various methods of data analysis, group sequential procedures for interim analysis, efficacy data evaluation, analysis of safety data, and more. Throughout, the book: * Surveys current and emerging clinical issues and newly developed statistical methods * Presents a critical review of statistical methodologies in various therapeutic areas * Features case studies from actual clinical trials * Minimizes the mathematics involved, making the material widely accessible * Offers each chapter as a self-contained entity *

Includes illustrations to highlight the text This monumental reference on all facets of clinical trials is important reading for physicians, clinical and medical researchers, pharmaceutical scientists, clinical programmers, biostatisticians, and anyone involved in this burgeoning area of clinical research. It can also be used as a textbook in graduate-level courses in the field.

Oral Bioavailability
Elsevier

The book also illustrates how bioavailability adjustments can be incorporated into risk assessments to generate risk-based cleanup values that are more site specific than those based on the default assumption of complete bioavailability. Although the book focuses on oral bioavailability of metals to human receptors, many of the basic principles described herein also can be applied to assessing bioavailability of organic compounds and for assessing bioavailability to ecological receptors."--BOOK JACKET.

Conduct and Analysis of Bioavailability and Bioequivalence Studies
CRC Press

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, prefomulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

FDA Bioequivalence Standards Wiley-Interscience

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of

pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

The Organic Chemistry of Drug Design and Drug Action CRC Press Maintaining a practical perspective, Bioequivalence and Statistics in Clinical Pharmacology, Second Edition explores statistics used in day-to-day clinical pharmacology work. The book is a starting point for those involved in such research and covers the methods needed to design, analyze, and interpret bioequivalence trials; explores when, how, and why these studies are performed as part of drug development; and demonstrates the methods using real world examples. Drawing on knowledge gained directly from working in the pharmaceutical industry, the authors set the stage by describing the general role of statistics. Once the foundation of clinical pharmacology drug development, regulatory applications, and the design and analysis of bioequivalence trials are established, including recent regulatory changes in design and analysis and in particular sample-size adaptation, they move on to related topics in clinical pharmacology involving the use of cross-over designs. These include, but are not limited to, safety studies in Phase I, dose-response trials, drug interaction trials, food-effect and combination trials, QTc and other pharmacodynamic equivalence trials, proof-of-concept trials, dose-proportionality trials, and vaccines trials. This second edition addresses several recent developments in the field, including new chapters on adaptive bioequivalence studies, scaled average bioequivalence testing, and vaccine trials. Purposefully designed to be instantly applicable, Bioequivalence and Statistics in Clinical Pharmacology, Second Edition provides examples of SAS and R code so that the analyses described can be immediately implemented. The authors have made extensive use of the proc mixed procedures available in SAS.

Bioavailability of Contaminants in Soils and Sediments CRC Press This authoritative volume explores advances in the techniques used to measure percutaneous penetration of drugs and chemicals to assess bioavailability and bioequivalence and discusses how they have been used in clinical and scientific investigations. Seven comprehensive sections examine topics including in vitro drug release, topical drugs products, clinical studies, and guidelines and workshop reports, among others. The book also describes how targeted transdermal drug delivery and more sophisticated mathematical modelling

can aid in understanding the bioavailability of transdermal drugs. The first edition of this book was an important reference guide for researchers working to define the effectiveness and safety of drugs and chemicals that penetrated the skin. This second edition contains cutting-edge advances in the field and is a key resource to those seeking to define the bioavailability and bioequivalence of percutaneously active compounds to improve scientific and clinical investigation and regulation.

Drug Bioavailability Wiley-Interscience

This practical book provides crucial information necessary to formulate diets with appropriate amounts of amino acids, minerals, and vitamins. The factors that influence how well animals obtain these critical nutrients and methods for determining bioavailability are reviewed in this comprehensive text. In addition, data from both ruminants and nonruminants are included as well as established estimates of bioavailability for particular feed stuffs and feed supplements.

Pharmaceutical Medicine Elsevier

This book focuses on analytical similarity assessment in biosimilar product development following the FDA's recommended stepwise approach for obtaining totality-of-the-evidence for approval of biosimilar products. It covers concepts such as the tiered approach for assessment of similarity of critical quality attributes in the manufacturing process of biosimilar products, models/methods like the statistical model for classification of critical quality attributes, equivalence tests for critical quality attributes in Tier 1 and the corresponding sample size requirements, current issues, and recent developments in analytical similarity assessment.

Dosage Form Design Parameters CRC Press

Bioavailability refers to the extent to which humans and ecological receptors are exposed to contaminants in soil or sediment. The concept of bioavailability has recently piqued the interest of the hazardous waste industry as an important consideration in deciding how much waste to clean up. The rationale is that if contaminants in soil and sediment are not bioavailable, then more contaminant mass can be left in place without creating additional risk. A new NRC report notes that the potential for the consideration of bioavailability to influence decision-making is greatest where certain chemical, environmental, and regulatory factors align. The current use of bioavailability in risk assessment and hazardous waste cleanup regulations is demystified, and acceptable tools and models for bioavailability assessment are discussed and ranked according to seven criteria. Finally, the intimate link between bioavailability and bioremediation is explored. The report concludes with suggestions for moving bioavailability forward in the regulatory arena for both soil and sediment cleanup.

Design and Analysis of Bioavailability and Bioequivalence Studies CRC Press

Published in 1994: This text focuses on the determination of bioequivalence between formulations that are pharmaceutically equivalent and

manufactured using acceptable chemistry, manufacturing and controls and in accordance with Good Manufacturing Practices.

The ADME Encyclopedia
Springer
Studies in bioequivalence are the commonly accepted method to demonstrate therapeutic equivalence between two medicinal products. Savings in time and cost are substantial when using bioequivalence as an established surrogate marker of therapeutic equivalence. For this reason the design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities. Bioequivalence Studies in Drug Development focuses on the planning, conducting, analysing and reporting of bioequivalence studies, covering all aspects required by regulatory authorities. This text presents the required statistical methods, and with an outstanding practical emphasis, demonstrates their applications through numerous examples using real data from drug development. Includes all the necessary pharmacokinetic background information. Presents parametric and nonparametric statistical techniques. Describes adequate methods for power and sample size determination. Includes appropriate presentation of results from bioequivalence studies. Provides a practical overview of the design and analysis of bioequivalence studies. Presents the recent developments in methodology, including population and individual bioequivalence. Reviews the regulatory guidelines for such studies, and the existing global discrepancies. Discusses the designs and analyses of drug-drug and food-drug interaction studies. Bioequivalence Studies in Drug Development is written in an accessible style that makes it ideal for pharmaceutical scientists, clinical pharmacologists, and medical practitioners, as well as biometricians working in the pharmaceutical industry. It will also be of great value for professionals from regulatory bodies assessing bioequivalence studies.

Bioequivalence Studies in Drug Development
John Wiley & Sons
Pharmaceutical formulations have evolved from simple and traditional systems to more modern and complex novel dosage forms. Formulation development is a tedious process and requires an enormous amount of effort from many different people. Developing a stable novel dosage form and further targeting it to the desired site inside the body has always been a challenge. The purpose of this book is to bring together scholarly articles that highlight recent developments and trends in pharmaceutical formulation science. Each article has been written by authors specializing in the subject area and hailing from top institutions around the world. The book has been written in a systematic and lucid style explaining all basic concepts and fundamentals in a very simple way. This book aims to serve the need of all individuals involved at any level in the pharmaceutical dosage form development. I sincerely hope that the book will be liked by inquisitive students and learned colleagues.

Pharmaceutical Quality

by Design Springer Science & Business Media The first edition of Design and Analysis of Cross-Over Trials quickly became the standard reference on the subject and has remained so for more than 12 years. In that time, however, the use of cross-over trials has grown rapidly, particularly in the pharmaceutical arena, and researchers have made a number of advances in both the theory and methods applicable to these trials. Completely revised and updated, the long-awaited second edition of this classic text retains its predecessor's careful balance of theory and practice while incorporating new approaches, more data sets, and a broader scope. Enhancements in the second edition include: A new chapter on bioequivalence Recently developed methods for analyzing longitudinal continuous and categorical data Real-world examples using the SAS system A comprehensive catalog of designs, datasets, and SAS programs available on a companion Web site at www.crcpress.com The authors' exposition gives a clear, unified account of the design and analysis of cross-over trials from a statistical perspective along with their methodological underpinnings. With SAS programs and a thorough treatment of design issues, Design and Analysis of Cross-Over Trials, Second Edition sets a new standard for texts in this area and undoubtedly will be of direct practical value for years to come.

Dosage Form Design Considerations Academic Press Although the Bioequivalence (BE) requirements in many global jurisdictions have much in common, differences in certain approaches and requirements such as definitions and terms, choice of comparator (reference) product, acceptance criteria, fasted and fed studies, single and multi-dose studies, biowaivers and products not intended for absorption into the systemic circulation (locally acting medicines and dosage forms), amongst others, provide food for thought that standardisation should be a high priority objective in order to result in a harmonized international process for the market approval of products using BE. An important objective of Bioequivalence Requirements in Various Global Jurisdictions is to attempt to gather the various BE requirements used in different global jurisdictions to provide a single source of relevant information. This information from, Brazil, Canada, China, European Union, India, Japan, MENA, Russia South Africa, the USA and WHO will be of value to drug manufacturers, regulatory agencies, pharmaceutical scientists and related health organizations and governments around the world in the quest to harmonize regulatory requirements for the market approval of generic products.

Vitamins In Foods Springer Standard medicinal chemistry courses and texts are organized by classes of drugs with an emphasis on descriptions of their biological and pharmacological effects. This book represents a new approach based on physical organic chemical principles and reaction mechanisms that allow the reader to extrapolate to many related classes of drug molecules. The Second Edition reflects

the significant changes in the drug industry over the past decade, and includes chapter problems and other elements that make the book more useful for course instruction. New edition includes new chapter problems and exercises to help students learn, plus extensive references and illustrations Clearly presents an organic chemist's perspective of how drugs are designed and function, incorporating the extensive changes in the drug industry over the past ten years Well-respected author has published over 200 articles, earned 21 patents, and invented a drug that is under consideration for commercialization **Bioequivalence Requirements in Various Global Jurisdictions** Academic Press

Preeminent Experts Update a Well-Respected BookTaking into account the regulatory and scientific developments that have occurred since the second edition, Design and Analysis of Bioavailability and Bioequivalence Studies, Third Edition provides a complete presentation of the latest progress of activities and results in bioavailability and bioequiva