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

Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

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.

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

Helps you choose the right computational tools and techniques to meet your drug design goals Computational Drug Design covers all of the major computational drug design techniques in use today, focusing on the process that pharmaceutical chemists employ to design a new drug molecule. The discussions of which computational tools to use and when and how to use them are all based on typical pharmaceutical industry drug design processes. Following an introduction, the book is divided into three parts: Part One, The Drug Design Process, sets forth a variety of design processes suitable for a number of different drug development scenarios and drug targets. The author demonstrates how computational techniques are typically used during the design process, helping readers choose the best computational tools to meet their goals. Part Two, Computational Tools and Techniques, offers a series of chapters, each one dedicated to a single computational technique. Readers discover the strengths and weaknesses of each technique. Moreover, the book tabulates comparative accuracy studies, giving readers an unbiased comparison of all the available techniques. Part Three, Related Topics, addresses new, emerging, and complementary technologies, including bioinformatics, simulations at the cellular and organ level, synthesis route prediction, proteomics, and prodrug approaches. The book's accompanying CD-ROM, a special feature, offers graphics of the molecular structures and dynamic reactions discussed in the book as well as demos from computational drug design software companies. Computational Drug Design is ideal for both students and professionals in drug design, helping them choose and take full advantage of the best computational tools available. Note: CD-ROM/DVD and other supplementary materials are not included as part of eBook file.

Drug Bioavailability

A Practical Approach

Design and Analysis of Bioavailability and Bioequivalence Studies, Second Edition, Revised and Expanded, by Shein-Chung Chow and Jen-Pei Liu

Recent Practices

Processes, Tools, and Applications

Design and Analysis of Bioavailability and Bioequivalence Studies

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.

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

Dosage Form Design Parameters, Volume II, 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

Economic evaluation has become an essential component of clinical trial design to show that new treatments and technologies offer value to payers in various healthcare systems. Although many books exist that address the theoretical or practical aspects of cost-effectiveness analysis, this book differentiates itself from the competition by detailing

Pharmaceutical Medicine

Innovative Thermal and Non-Thermal Processing, Bioaccessibility and Bioavailability of Nutrients and Bioactive Compounds

Methodologies and Recent Developments

Computational Drug Design

FDA Bioequivalence Standards

Using time-to-event analysis methodology requires careful definition of the event, censored observation, provision of adequate follow-up, number of events, and independence or "noninformativeness" of the censoring mechanisms relative to the event. Design and Analysis of Clinical Trials with Time-to-Event Endpoints provides a thorough presentation of the design, monitoring, analysis, and interpretation of clinical trials in which time-to-event is of critical interest. After reviewing time-to-event endpoint methodology, clinical trial issues, and the design and monitoring of clinical trials, the book focuses on inferential analysis methods, including parametric, semiparametric, categorical, and Bayesian methods; an alternative to the Cox model for small samples; and estimation and testing for change in hazard. It then presents descriptive and graphical methods useful in the analysis of time-to-event endpoints. The next several chapters explore a variety of clinical trials, from analgesic, antibiotic, and antiviral trials to cardiovascular and cancer prevention, prostate cancer, astrocytoma brain tumor, and chronic myelogonous leukemia trials. The book then covers areas of drug development, medical practice, and safety assessment. It concludes with the design and analysis of clinical trials of animals required by the FDA for new drug applications. Drawing on the expert contributors' experiences working in biomedical research and clinical drug development, this comprehensive resource covers an array of time-to-event methods and explores an assortment of real-world applications.

As the development of medicines has become more globalized, the geographic variations in the efficacy and safety of pharmaceutical products need to be addressed. To accelerate the product development process and shorten approval time, researchers are beginning to design multiregional trials that incorporate subjects from many countries around the world under the same protocol. Design and Analysis of Bridging Studies addresses the issues arising from bridging studies and multiregional clinical trials. For bridging studies, the book explores ethnic sensitivity, the necessity of bridging studies, types of bridging studies, and the assessment of similarity between regions based on bridging evidence. For multiregional clinical trials, the text considers regional differences, assesses the consistency of treatment effect across regions, and discusses sample size determination for each region. Taking into account the International Conference Harmonisation (ICH) E5 framework for bridging studies, the book provides a unified summary of the growing literature and research activities in this area. It covers the regulatory requirements, scientific and practical issues, and statistical methodology for designing and evaluating bridging studies and multiregional clinical trials, with the goal of inspiring new research activities in the field.

A state-of-the-art handbook of statistical analysis for use in the pharmaceutical industry. Areas covered in this reference/text include: bioavailability, repeated-measures designs, dose-response, population models, multicenter trials, handling dropouts, survival analysis, robust data analysis, cate

Generics and Bioequivalence provides a clear, insightful, and in-depth analysis of the many complex issues encountered in the determination of drug bioequivalence. Included are timely updates on many controversial and newly emerging areas in the design and analysis of bioavailability and bioequivalence studies. This new reference was prepared by a group of authorities from academe, industry, and government and can be easily understood by students and experienced scientists alike. Topics presented include the role of single and multiple dosing in the determination of bioequivalence, the role of metabolites in assessing bioequivalence, stereochemical considerations in bioequivalence evaluation, uses of animal models, pharmacodynamics, and statistics. The analysis of pharmacodynamic data (especially when plasma levels are unavailable) is covered, and the nascent importance of individual bioequivalence is examined.

Pharmacokinetics in Drug Development

Atkinson's Principles of Clinical Pharmacology

Design and Analysis of Clinical Trials

Bioavailability of Contaminants in Soils and Sediments

Handbook of Bioequivalence Testing

Drug-like Properties: Concepts, Structure Design and Methods

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.

This comprehensive reference provides an in-depth discussion on state-of-the-art regulatory science in bioequivalence. In sixteen chapters, the volume explores a broad range of topics pertaining to bioequivalence, including its origin and principles, statistical considerations, food effect studies, conditions for waivers of bioequivalence studies, Biopharmaceutics Classification Systems, Biopharmaceutics Drug Disposition Classification System, bioequivalence modeling/simulation and best practices in bioanalysis. It also discusses bioequivalence studies with pharmacodynamic and clinical endpoints as well as bioequivalence approaches for highly variable drugs, narrow therapeutic index drugs, liposomes, locally acting gastrointestinal drug products, topical products and nasal and inhalation products. FDA Bioequivalence Standards is written by FDA regulatory scientists who develop regulatory policies and conduct regulatory assessment of bioequivalence. As such, both practical case studies and fundamental science are highlighted in these chapters. The book is a valuable resource for scientists who work in the pharmaceutical industry, regulatory agencies and academia as well as undergraduate and graduate students looking to expand their knowledge about bioequivalence standards.

"Provides a comprehensive summary of the continuously growing literature and research activities on the regulatory requirements, scientific and practical issues, and statistical methodology of the design and analysis of bioavailability and bioequivalence studies. Includes several new chapters."

The third edition of this introductory text covers the factors which influence the release of the drug from the drug product and how the body handles the drug. A stronger focus has been placed on the basics with clear explanations and illustrated examples. There is also more information on statistics and population pharmacokinetics and new chapters on drug distribution, computer applications, enzyme kinetics and pharmacokinetics models.

Bioavailability of Nutrients for Animals

Statistical Design and Analysis in Pharmaceutical Science

Pharmaceutical Theory and Practice

Statistical Methodology in the Pharmaceutical Sciences

Vitamins In Foods

Estimation of Solubility, Permeability, Absorption and Bioavailability

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.

Emphasizing the role of good statistical practices (GSP) in drug research and formulation, this book outlines important statistics applications for each stage of pharmaceutical development to ensure the valid design, analysis, and assessment of drug products under investigation and establish the safety and efficacy of pharmaceutical compounds. Cove

The increased use of non-inferiority analysis has been accompanied by a proliferation of research on the design and analysis of non-inferiority studies. Using examples from real clinical trials, Design and Analysis of Non-Inferiority Trials brings together this body of research and confronts the issues involved in the design of a non-inferiority trial. Each chapter begins with a non-technical introduction, making the text easily understood by those without prior knowledge of this type of trial. Topics covered include: A variety of issues of non-inferiority trials, including multiple comparisons, missing data, analysis population, the use of safety margins, the internal consistency of non-inferiority inference, the use of surrogate endpoints, trial monitoring, and equivalence trials Specific issues and analysis methods when the data are binary, continuous, and time-to-event The history of non-inferiority trials and the design and conduct considerations for a non-inferiority trial The strength of evidence of an efficacy finding and how to evaluate the effect size of an active control therapy A comprehensive discussion on the purpose and issues involved with non-inferiority trials, Design and Analysis of Non-inferiority Trials will assist current and future scientists and statisticians on the optimal design of non-inferiority trials and in assessing the quality of non-inferiority comparisons done in practice.

These volumes are designed to be the most complete guide to pharmacokinetics (PK) and its role in drug development. They fill a gap between the academic science and the practical application of that knowledge in drug development. Volume 1 discusses the role that PK plays in selected clinical study designs. Volume 2 details the key regulatory and development paradigms in which PK supplements decision-making during drug development.

Generic Drug Product Development

Pharmaceutical Formulation Design

Design & Analysis of Clinical Trials for Economic Evaluation & Reimbursement

Amino Acids, Minerals, Vitamins

An Underestimated Class of Bioactive Plant Polyphenols

A Guide for Computational and Medicinal Chemists

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.

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made

Design and Analysis of Bioavailability and Bioequivalence StudiesCRC Press

Of the thousands of novel compounds that a drug discovery project team invents and that bind to the therapeutic target, typically only a fraction of these have sufficient ADME/Tox properties to become a drug product. Understanding ADME/Tox is critical for all drug researchers, owing to its increasing importance in advancing high quality candidates to clinical studies and the processes of drug discovery. If the properties are weak, the candidate will have a high risk of failure or be less desirable as a drug product. This book is a tool and resource for scientists engaged in, or preparing for, the selection and optimization process. The authors describe how properties affect in vivo pharmacological activity and impact in vitro assays. Individual drug-like properties are discussed from a practical point of view, such as solubility, permeability and metabolic stability, with regard to fundamental understanding, applications of property data in drug discovery and examples of structural modifications that have achieved improved property performance. The authors also review various methods for the screening (high throughput), diagnosis (medium throughput) and in-depth (low throughput) analysis of drug properties. * Serves as an essential working handbook aimed at scientists and students in medicinal chemistry * Provides practical, step-by-step guidance on property fundamentals, effects, structure-property relationships, and structure modification strategies * Discusses improvements in pharmacokinetics from a practical chemist's standpoint

Validation, Process Controls, and Stability

Chemistry and Biology of Ellagitannins

Statistics in Drug Research

The Design and Manufacture of Medicines

Dosage Form Design Parameters

Analysis, Bioavailability, and Stability

Pharmacokinetics and Toxicokinetic Considerations explains the central principles, cutting-edge methodologies, and incipient thought processes applied to toxicology research. As part of the Advances in Pharmaceutical Product Development and Research series, the book provides expert literature on dose, dosage regimen and dose adjustment, medication errors, and approaches for its prevention, the concept of pharmacotherapy, and managed care in clinical interventions. It expounds on strategies to revamp the pharmacokinetics of the drug and the factors affecting the stability of drugs and their metabolites in biological matrices. Finally, the book offers focused elaborations on various bioanalytical methods for bioavailability and bioequivalence assessment and integrates the wide-ranging principles and concepts shared by toxicokinetics and pharmacodynamics as mutual crosstalk rather than isolated observations. It will be helpful to researchers and advanced students working in the pharmaceutical, cosmetics, biotechnology, food, and related industries including toxicologists, pharmacists, and pharmacologists. Allows readers to systematically integrate up-to-date research findings into their laboratory work Presents focused explorations of bioanalytical methods for bioavailability and bioequivalence assessment Provides clinical applications of concepts

The breadth of the pharmaceutical medicine can be daunting, but this book is designed to navigate a path through the speciality. Providing a broad overview of all topics relevant to the discipline of pharmaceutical medicine, it gives you the facts fast, in a user-friendly format, without having to dive through page upon page of dense text. With 136 chapters spread across 8 sections, the text offers a thorough grounding in issues ranging from medicines regulation to clinical trial design and data management. This makes it a useful revision aid for exams as well as giving you a taster of areas of pharmaceutical medicine adjacent to your current role. For healthcare professionals already working in the field, this book offers a guiding hand in difficult situations as well as supplying rapid access to the latest recommendations and guidelines. Written by authors with experience in the industry and drug regulation, this comprehensive and authoritative guide provides a shoulder to lean on throughout your pharmaceutical career.

Drug Discovery and Evaluation has become a more and more difficult, expensive and time-consuming process. The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise we have designed a book series "Drug Discovery and Evaluation" in the form of a recommendation document. The methods to detect drug targets are described in the first volume of this series "Pharmacological Assays" comprising classical methods as well as new technologies. Before going to man, the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology. These preclinical methods are described in the second volume „Safety and Pharmacokinetic Assays". Only then are first studies in human beings allowed. Special rules are established for Phase I studies. Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects. Special studies according to various populations and different therapeutic indications are necessary. These items are covered in the third volume: „Methods in Clinical Pharmacology".

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 Considerations

Pharmacokinetics and Toxicokinetic Considerations - Vol II

Part B. Oral Modified Release Formulations

Conduct and Analysis of Bioavailability and Bioequivalence Studies

International Regulatory Requirements for Bioequivalence

Aulton's Pharmaceutics

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.

Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

Atkinson’s Principles of Clinical Pharmacology, Fourth Edition is the essential reference on the pharmacologic principles underlying the individualization of patient therapy and contemporary drug development. This well-regarded survey continues to focus on the basics of clinical pharmacology for the development, evaluation and clinical use of pharmaceutical products while also addressing the most recent advances in the field. Written by leading experts in academia, industry, clinical and regulatory settings, the fourth edition has been thoroughly updated to provide readers with an ideal reference on the wide range of important topics impacting clinical pharmacology. Presents the essential knowledge for effective practice of clinical pharmacology Includes a new chapter and extended discussion on the role of personalized and precision medicine in clinical pharmacology Offers an extensive regulatory section that addresses US and international issues and guidelines Provides extended coverage of earlier chapters on transporters, pharmacogenetics and biomarkers, along with further discussion on "Phase 0" studies (microdosing) and PBPK

The Design, Analysis and Implementation of the Bioavailability Study

Design and Analysis of Clinical Trials with Time-to-Event Endpoints

Design and Analysis of Bridging Studies

Design and Analysis of Non-Inferiority Trials

An Applied Approach Using SAS & STATA

Sample Size Calculations in Clinical Research

"Offers a comprehensive, unified presentation of statistical designs and methods of analysis for all stages of pharmaceutical development--emphasizing biopharmaceutical applications and demonstrating statistical techniques with real-world examples."

Sample size calculation plays an important role in clinical research. It is not uncommon, however, to observe discrepancies among study objectives (or hypotheses), study design, statistical analysis (or test statistic), and sample size calculation. Focusing on sample size calculation for studies conducted during the various phases of clinical research and development, Sample Size Calculation in Clinical Research explores the causes of discrepancies and how to avoid them. This volume provides formulas and procedures for determination of sample size required not only for testing equality, but also for testing non-inferiority/superiority, and equivalence (similarity) based on both untransformed (raw) data and log-transformed data under a parallel-group design or a crossover design with equal or unequal ratio of treatment allocations. It contains a comprehensive and unified presentation of statistical procedures for sample size calculation that are commonly employed at various phases of clinical development. Each chapter includes, whenever possible, real examples of clinical studies from therapeutic areas such as cardiovascular, central nervous system, anti-infective, oncology, and women's health to demonstrate the clinical and statistical concepts, interpretations, and their relationships and interactions. The book highlights statistical procedures for sample size calculation and justification that are commonly employed in clinical research and development. It provides clear, illustrated explanations of how the derived formulas and/or statistical procedures can be used.

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.

Innovative Thermal and Nonthermal Processing, Bioacessibility and Bioavailability of Nutrients and Bioactive Compounds presents the implications of conventional and innovative processing on the nutritional and health aspects of food products. Chapters cover the relationship between gastronomic science, nutrition and food science in the development of healthy products, introduce the most commonly used conventional and innovative approaches to preserve foods and extract valuable compounds, describe how processing affects bioavailability and bioaccessibility of lipids, particularly fatty acids, protein, amino acids and carbohydrates, and discuss how processing affects bioavailability and bioaccessibility of minerals, water-soluble vitamins, and fat soluble vitamins. Final sections cover processing, bioavailability and bioaccessibility of bioactive compounds, describing how processing (conventional and non-conventional) is affecting to bioavailability and bioaccessibility of bioactive sulphur compounds, polyphenols, flavonoids, and bioactive peptides. Presents the implications of conventional and innovative processing on the nutritional and health aspects of food products Introduces the most commonly used conventional and innovative approaches to preserve foods and extract valuable compounds Explains how processing (conventional and non-conventional) affects the bioavailability and bioaccessibility of bioactive sulphur compounds, polyphenols, flavonoids and bioactive peptides

Statistical Design and Analysis of Stability Studies

Drug Discovery and Evaluation: Methods in Clinical Pharmacology

Clinical Study Design and Analysis

from ADME to Toxicity Optimization

Analytical Similarity Assessment in Biosimilar Product Development

Pharmacokinetic Analysis

This insightful work provides a useful introduction to the very large and important field of pharmacokinetics. The authors have selected the Time Constant Approach as a unifying view within which to present important application areas. In addition to providing consistency, their approach provides the novice with an intuitive time view that is meaningful from the outset. This approach allows one to get a "feel" for the data and to relate it to other data in a direct and accessible manner. The Time Constant Approach provides a synthesis of the noncompartmental and compartmental methods, with the advantages of both. It starts by defining a physiologically meaningful model based on the pharmacokinetic processes involved. The Time Constant Approach recognizes pharmacokinetics as a number of processes that move drugs between physiological compartments, each process occurring at its own characteristic length of time, to correlate descriptive pharmacokinetic events with time constants of pharmacokinetic processes. While analogous to the three most common testing approaches for pharmacokinetics (the noncompartmental, compartmental and statistical moment approaches) the Time Constant Approach possesses many advantages.

This book is the first of its kind that focuses on the chemistry and biology of ellagitannins, a special class of naturally occurring polyphenols which have so far not received the attention they deserve. These polyphenolic substances are found in many plants, including numerous food sources. They not only exhibit unique structural features that fascinate most chemists who are aware of their existence, but also express remarkable biological activities that have yet to attract the interest of the pharmaceutical industry. This is surprising because ellagitannins have been identified as active principles in traditional Chinese medicines. The principal aim of this book is to set the record straight. Most, if not all, worldwide experts in each aspect of the chemistry and biology of this underestimated

class of natural products have contributed to this book. It covers topics such as their structural determination and natural occurrence; the most up-to-date knowledge of their biosynthesis; the current state of the art of their total chemical synthesis; their main physicochemical properties and principal biological activities; their presence in food and beverages; and their related health effects. All together, nine chapters compose this book whose content is placed into historical perspective in a yet inspiring preface written by one of the pioneers in modern polyphenol research, Professor Edwin Haslam. This book will be useful not only to scientists involved in natural product research, but also to lecturers and their students as a source of key references and/or a textbook.

Concept and Methodologies

Generics and Bioequivalence

Developing Solid Oral Dosage Forms

Applied Biopharmaceutics and Pharmacokinetics