
Handbook Of Bioequivalence Testing Second Edition Drugs And The Pharmaceutical Sciences

Biodrug Delivery Systems
Fundamentals of Modern Bioprocessing
Handbook of Pharmaceutical Manufacturing Formulations, Third Edition
Generic Drug Product Development
Handbook of Pharmaceutical Manufacturing Formulations
Bioequivalence and Statistics in Clinical Pharmacology
Handbook of Preformulation
Fundamentals, Applications and Clinical Development
A Nonlinear Analysis
Developing Solid Oral Dosage Forms
Handbook of Dissolution Testing
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Pharmaceutical Statistics
Chemical, Biological, and Botanical Drugs, Second Edition
Handbook of Basic Pharmacokinetics-- Including Clinical Applications
Generic Drug Product Development
Basic Principles and Systems, Fifth Edition
International Pharmaceutical Product Registration, Second Edition
Handbook of Pharmaceutical Granulation Technology
The FDA Perspective
Pharmaceutical Process Engineering, Second Edition
Basic Pharmacokinetics, Second Edition
Polymorphism in Pharmaceutical Solids
Modern Pharmaceutics, Two Volume Set
Chemical, Biological, and Botanical Drugs, Second Edition
FDA Bioequivalence Standards
Strategic Elements
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A Practical Guide from Candidate Drug Selection to Commercial Dosage Form
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MATHEWS TOWNSEND

Biodrug Delivery Systems CRC Press

Biological drug and vaccine manufacturing has quickly become one of the highest-value fields of bioprocess engineering, and many bioprocess engineers are now finding job opportunities that have traditionally gone to chemical engineers. *Fundamentals of Modern Bioprocessing* addresses this growing demand. Written by experts well-established in the field, this book connects the principles and applications of bioprocessing engineering to healthcare product manufacturing and expands on areas of opportunity for qualified bioprocess engineers and students. The book is divided into two sections: the first half centers on the engineering fundamentals of bioprocessing; while the second half serves as a handbook offering advice and practical applications. Focused on the fundamental principles at the core of this discipline, this work outlines every facet of design, component selection, and regulatory concerns. It discusses the purpose of bioprocessing (to produce products suitable for human use), describes the manufacturing technologies related to bioprocessing, and explores the rapid expansion of bioprocess engineering applications relevant to health care product manufacturing. It also considers the future of bioprocessing—the use of disposable components (which is the fastest growing area in the field of bioprocessing) to replace traditional stainless steel. In addition, this text: Discusses the many types of genetically modified organisms Outlines laboratory techniques Includes the most recent developments Serves as a reference and contains an extensive bibliography Emphasizes biological manufacturing using recombinant processing, which begins with creating a genetically modified organism using recombinant techniques *Fundamentals of Modern Bioprocessing* outlines both the principles and applications of bioprocessing engineering related to healthcare product manufacturing. It lays out the basic concepts, definitions, methods and applications of bioprocessing. A single volume comprehensive reference developed to meet the needs of students with a bioprocessing background; it can also be used as a source for professionals in the field.

Fundamentals of Modern Bioprocessing Handbook of Bioequivalence Testing, Second Edition

The over-riding premise for biotechnology in this book is bringing novel products to market to substantially advance patient care and disease mitigation. Biotechnology, over its relatively brief existence of 40 years, has experienced a mercurial growth. The vast educational need for biotechnology information in this rapidly burgeoning field is a basic rationale here. However a more prominent underpinning is that, bringing biotech products to market for patient care involves success in the following four areas of engagement simultaneously - scientific advances for healthcare technologies, novel and varied products for untreated diseases, regulatory authorities,

and biotech companies. Features Comprehensive coverage of biotechnology science topics used in development and manufacturing Addresses all the scientific technologies within biotechnology responsible for products on the market and the pipeline Presents business issues such as marketing and sales of the products, as well as companies engaged, and how biotech business has evolved **Handbook of Pharmaceutical Manufacturing Formulations, Third Edition** 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. Generic Drug Product Development CRC Press

Preformulation studies are the physical, chemical, and biological studies needed to characterize a drug substance for enabling the proper design of a drug product, whereas the effectiveness of a drug product is determined during the formulation studies phase. Though the two disciplines overlap in practice, each is a significantly distinct phase of new drug development. Entirely focused on preformulation principles, this fully revised and updated *Handbook of Preformulation: Chemical, Biological, and Botanical Drugs, Second Edition* provides detailed descriptions of preformulation methodologies, gives a state-of-the-art description of each technique, and lists the currently available tools useful in providing a comprehensive characterization of a new drug entity.

Handbook of Pharmaceutical Manufacturing Formulations CRC Press

Biodrug Delivery Systems: Fundamentals, Applications and Clinical Development presents the work of an international group of leading experts in drug development and biopharmaceutical science who discuss the latest advances in biodrug delivery systems and associated techniques. The book

discusses components of successful formulation, delivery, and p
Bioequivalence and Statistics in Clinical Pharmacology CRC Press

With over 100 illustrations, Volume 1 addresses the core disciplines of pharmaceuticals (absorption, PK, excipients, tablet dosage forms, and packaging), and explores the challenges and paradigms of pharmaceuticals. Key topics in Volume 1 include: • principles of drug absorption, chemical kinetics, and drug stability • pharmacokinetics • the effect of route of administration and distribution on drug action • in vivo imaging of dose forms: gamma scintigraphy, PET imaging NMR, MRI, etc. • powder technology • excipient design and characterization • preformulation • optimization techniques in pharmaceutical formulation and processing • disperse and surfactant systems • the solid state, tablet dosage forms, coating processes, and hard and soft shell capsules • parenteral products
Handbook of Preformulation CRC Press

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.

Fundamentals, Applications and Clinical Development CRC Press

No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster

A Nonlinear Analysis CRC Press

The assessment of bioequivalence is an important process whereby the bioavailability of a generic drug product is compared with its brand-name counterpart. Generic pharmaceutical products must be approved as therapeutic equivalents to the brand name alternative in order to be interchangeable. The demonstration of bioequivalence is an important component of therapeutic equivalence. Bioequivalence studies are very expensive, time consuming and always have the possibility of failure. The objective of this textbook is to describe some of those specific bioequivalence issues which need to be considered for the design and conduct of bioequivalence studies. By exploring scientific, legal, and international regulatory challenges, *Generic Drug Development*, discusses the use of alternative approaches to the measurement of plasma drug concentrations for the demonstration of bioequivalence, and covers bioequivalence procedures for

drug products that are not easily assessed - based upon the physical and chemical properties of the active drug and the nature of the drug product.

Developing Solid Oral Dosage Forms CRC Press

With step-by-step methods of drug production and knowledge of major unit operations and key concepts of pharmaceutical engineering, this guide will help to improve communication among the varied professionals working in the pharmaceutical industry. Key features: REVISION OF A BESTSELLER - Updates include recent advances in the field to keep pharmaceutical scientists and technologists up-to-date IDEAL INTRODUCTORY TEXT - Covers basic engineering principles, drug production, and development processes, so scientists can easily convert bulk pharmaceutical products into patient-ready dosage forms NEW INFORMATION - on quality principles that include quality by design; mathematical and statistical approaches to experimental design; computer aided design; and PAT (process analytical technology) keeps professionals at the forefront of their field COMPREHENSIVE COVERAGE - Step-by-step methods of drug production, knowledge of major unit operations, and key concepts of pharmaceutical engineering will help to improve communication among the varied professionals working in the pharmaceutical industry

Handbook of Dissolution Testing CRC Press

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

Handbook of Bioequivalence Testing CRC Press

Handbook of Bioequivalence Testing, Second Edition CRC Press

Generic Drug Product Development CRC Press

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

Specialty Dosage Forms CRC Press

When a biological drug patent expires, alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps. The assessment of biosimilarity and interchangeability is also complicated and difficult. *Biosimilar Drug Product Development* presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre- and post-approval issues.

Pharmaceutical Statistics CRC Press

Before now, biological systems could only be expressed in terms of linear relationships, however, as knowledge grows and new techniques of analysis on biological systems is made available, we are realizing the non-linearity of these systems. The concepts and techniques of nonlinear analysis allow for more realistic and accurate models in science. *The Future of Pharmaceuticals: A Nonlinear Analysis* provides an opportunity to understand the non-linearity of biological systems and its application in various areas of science, primarily pharmaceutical sciences. This book will benefit professionals in pharmaceutical industries, academia, and policy who are interested in an entirely new approach to how we will treat disease in the future. Key Features: Addresses a new approach of nonlinear analysis. Applies a theory of projection to chalk out the future, instead of basing on linear evolution. Provides an opportunity to better understand the non-linearity in biological systems and its applications in various areas of science, primarily pharmaceutical sciences. Helps change the thought process for those looking for answers to their questions which they do not find in the linear relationship approach. Encourages a broader perspective for the creative process of drug development.

Chemical, Biological, and Botanical Drugs, Second Edition CRC Press

The *Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume One, Compressed Solid Products* is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this first volume of a six-volume set, compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent.

Handbook of Basic Pharmacokinetics-- Including Clinical Applications CRC Press

Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies. The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update. This cutting-edge resource includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission. The format, specification, and technical requirements of the e-CTD, the electronic version of CTD, are also thoroughly discussed. The book is organized into six highly practical segments: Part I: CTD, eCTD, Module 1, and Environmental Risk Assessment Part II: CTD Summaries Part III: Quality Topics Part IV: Nonclinical Topics Part V: Clinical Topics Part VI: Other Topics (including drug-device combination products) This text is a must-have for those in the pharmaceutical industry determining regulatory requirements for the major world markets in Europe, the US, Canada, and Japan.

Generic Drug Product Development CRC Press

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

Basic Principles and Systems, Fifth Edition CRC Press

The first edition of *Pharmaceutical Extrusion Technology*, published in 2003, was deemed the seminal book on pharmaceutical extrusion. Now it is expanded and improved, just like the usage of extrusion has expanded, improved and evolved into an accepted manufacturing technology to continuously mix active pharmaceutical ingredients with excipients for a myriad of traditional and novel dosage forms. *Pharmaceutical Extrusion Technology, Second Edition* reflects how this has spawned numerous research activities, in addition to hardware and process advancements. It offers new authors, expanded chapters and contains all the extrusion related technical information necessary for the development, manufacturing, and marketing of pharmaceutical dosage forms. Key Features: Reviews how extrusion has become an accepted technology to continuously mix active pharmaceutical ingredients with excipients Focuses on equipment and process technology Explains various extrusion system configurations as a manufacturing methodology for a variety of dosage forms Presents new opportunities available only via extrusion and future trends Includes contributions of experts from the process and equipment fields

International Pharmaceutical Product Registration, Second Edition CRC Press

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

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