

Pharmaceutical Stress Testing Predicting Drug Degradation Second Edition Drugs And The Pharmaceutical Sciences

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[Biodrug Delivery Systems](#) - Mariko Morishita 2016-04-19

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

Advanced Drug Formulation Design to Optimize Therapeutic Outcomes - Robert O. Williams 2007-09-25

This title demonstrates how advanced formulation designs and delivery technologies can be used to improve drug efficacy and treatment outcomes in particular therapeutic categories or disease states. It discusses nanoparticle systems for cancer treatments, and also presents cutting edge immono-regulation agents for transplantation and the local targ

Drug-like Properties: Concepts, Structure Design and Methods - Li Di 2010-07-26

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
Generic Drug Product Development - Leon Shargel 2013-10-24

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. *Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition* presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval. Major topics discussed include: Active pharmaceutical ingredients Experimental formulation development, including a new section on Quality by Design (QbD) Scale-up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post-approval changes Post-marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined. The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition - Graham P. Bunn 2019-02-04

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.

Pharmaceutical Extrusion Technology - Isaac Ghebre-Sellassie 2018-03-05

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

Polymorphism in Pharmaceutical Solids - Harry G. Brittain 2018-11-12

Using clear and practical examples, *Polymorphism of Pharmaceutical Solids, Second Edition* presents a comprehensive examination of polymorphic behavior in pharmaceutical development that is ideal for pharmaceutical development scientists and graduate students in pharmaceutical science. This edition focuses on pharmaceutical aspects of polymorphism a

Biotechnology - Ronald P. Evens 2020-06-04

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

Preformulation in Solid Dosage Form Development - Moji

Christianah Adeyeye 2008-01-07

During the onset of any clinical trial there are many factors and variables to consider. Funding, time restraints, and regulatory agency guidelines are factors that often influence which variables will be studied, leaving other important information out of the study. Preformulation in Solid Dosage Form Development covers every topic of critical importance to the preformulation stages of drug development. Serving as a handbook or stand-alone reference, this text equips those in academia and the pharmaceutical industry with both basic and applied principles for the characterization of drugs, excipients, and products, and deals with the issues relating to predictability, identification, and product development during preformulation stages through Phase I of clinical trials. With contributions from an international panel of experts in the field, this guide: outlines an updated preformulation program for modern drug development issues that includes particle morphology, characterization, thermal analysis, and solubility methods contains rational designs for the structure of formulation studies covers the importance of preformulation design using artificial neural networks and computational prediction techniques, and examines the concepts of preliminary-preformulation discusses the typical drug-excipient interactions that could occur during the course of development and methods of characterization includes novel methods to determine the physical and chemical stability of new

formulations reviews the structure, content, and format of the preformulation report examines the significance of drug substance physiochemical properties, in regulatory quality by design
Pharmaceutical Stress Testing - Steven W. Baertschi 2011-07-27
The second edition of Pharmaceutical Stress Testing: Predicting Drug Degradation provides a practical and scientific guide to designing, executing and interpreting stress testing studies for drug substance and drug product. This is the only guide available to tackle this subject in-depth. The Second Edition expands coverage from chemical stability into the physical aspects of stress testing, and incorporates the concept of Quality by Design into the stress testing construct / framework. It has been revised and expanded to include chapters on large molecules, such as proteins and antibodies, and it outlines the changes in stress testing that have emerged in recent years. Key features include: A renowned Editorial team and contributions from all major drug companies, reflecting a wealth of experience. 10 new chapters, including Stress Testing and its relationship to the assessment of potential genotoxic degradants, combination drug therapies, proteins, oligonucleotides, physical changes and alternative dosage forms such as liposomal formulations Updated methodologies for predicting drug stability and degradation pathways Best practice models to follow An expanded Frequently Asked Questions section This is an essential reference book for Pharmaceutical Scientists and those working in Quality Assurance and Drug Development (analytical sciences, formulations, chemical process, project management).

New Drug Approval Process - Richard A. Guarino 2016-04-19

The thoroughly revised Fifth Edition of New Drug Approval Process supplies readers with the latest global changes that affect pharmaceutical product approval and influence how new products are researched and marketed. Updated chapters include: advances in international regulatory requirements, including ICH guidelines and harmonization a step-by-step

Pharmaceutical Preformulation and Formulation - Mark Gibson 2016-04-19

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 Pharmaceutical Granulation Technology - Dilip M. Parikh 2016-04-19

The Third Edition presents all pharmaceutical industry personnel and those in academia with critical updates on the recent advances in granulation technology and changes in FDA regulatory guidelines. Addressing precisely how these recent innovations and revisions affect unit operation of particle generation and granulation, this text assists the re

Pharmaceutical Process Engineering, Second Edition - Anthony J. Hickey 2016-03-09

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

Biosimilar Drug Product Development - Laszlo Endrenyi 2017-02-24
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 - Sanford Bolton 2009-12-23

Through the use of practical examples and solutions, *Pharmaceutical Statistics: Practical and Clinical Applications, Fifth Edition* provides the most complete and comprehensive guide to the various statistical applications and research issues in the pharmaceutical industry, particularly in clinical trials and bioequivalence studies.

Good Design Practices for GMP Pharmaceutical Facilities - Terry Jacobs 2016-08-19

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

The Art and Science of Dermal Formulation Development - Marc B. Brown 2019-03-01

The Art and Science of Dermal Formulation Development is a comprehensive guide to the theory and practice of transdermal and topical formulation development, covering preclinical studies, evaluation, and regulatory approval. It enables the reader to understand the opportunities and challenges in developing products and how risks can be mitigated. Over the last 25 years, expertise in this area has declined whilst drug delivery systems for other administration routes have developed significantly. The advantages offered by transdermal and topical drug delivery remain compelling for sectors including the pharmaceutical industry, personal care, and cosmetics. This text addresses the dearth of expertise and discusses how skin can be a route of delivery and the processes in formulation development, but how such an application is very different to that used for oral, IV, and other administration routes. Key Features: Presents a practical guide for both industry and academia Focuses on and draws together the fundamental principles behind transdermal and topical drug delivery Illustrates the practicalities of formulation design using key case studies Gives an understanding of the skin as a route of delivery and how formulation development for such application differs from that for other administration routes

Pharmaceutical Powder Compaction Technology, Second Edition - Metin Çelik 2016-04-19

Compaction of powder constituents—both active ingredient and excipients—is examined to ensure consistent and reproducible disintegration and dispersion profiles. Revised to reflect modern pharmaceutical compacting techniques, this second edition of Pharmaceutical Powder Compaction Technology guides pharmaceutical engineers, formulation scientists, and product development and quality assurance personnel through the compaction formulation process and application. This unique reference covers: The physical structure of pharmaceutical compacts Bonding phenomena that occur during powder compaction Compression mechanisms of pharmaceutical particles

Theories and basic principles of powder compaction New topics include: Compaction data analysis techniques The migration of powder constituents into commercial manufacture Instrumentation for compaction Compaction functionality testing, which is likely to become a USP requirement Design space for compaction Metrics required for scalability in tablet compression Interactive compaction and preformulation database for commonly used excipients

Pharmaceutical Inhalation Aerosol Technology, Third Edition - Anthony J. Hickey 2019-03-26

This fully revised and updated third edition of Pharmaceutical Inhalation Aerosol Technology encompasses the scientific and technical foundation for the rationale, design, componentry, assembly and quality performance metrics of therapeutic inhalers in their delivery of pharmaceutical aerosols to treat symptoms or the underlying causes of disease. It focuses on the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery. The expanded scope considers previously unaddressed aspects of pharmaceutical inhalation aerosol technology and the patient interface by including aerosol delivery, lung deposition and clearance that are used as measures of effective dose delivery. Key Features: Provides a thoroughly revised and expanded reference with authoritative discussions on the physiologic, pharmacologic, metabolic, molecular, cellular and physicochemical factors, influencing the efficacy and utilization of pharmaceutical aerosols Emphasizes the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery Addresses the physics, chemistry and engineering principles while establishing disease relevance Expands the 'technology' focus of the original volumes to address the title more directly Offers an impressive breadth of coverage as well as an international flavour from outstanding editors and contributors

Handbook of Bioequivalence Testing - Sarfaraz K. Niazi 2007-08-22
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

Generic Drug Product Development - Isadore Kanfer 2007-11-15

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.

Pharmaceutical Dissolution Testing - Jennifer J. Dressman 2005-07-08

An expertly written source on the devices, systems, and technologies used in the dissolution testing of oral pharmaceutical dosage forms, this reference provides reader-friendly chapters on currently utilized equipment, equipment qualification, consideration of the gastrointestinal physiology in test design, the analysis and interpretation of data and procedure automation - laying the foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract.

Hot-Melt Extrusion - Dennis Douroumis 2012-04-24

Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the

preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. *Hot-Melt Extrusion: Pharmaceutical Applications* covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale-up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy *Hot-Melt Extrusion: Pharmaceutical Applications* is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series *Advances in Pharmaceutical Technology*. Find out more about the series here.

Pharmaceutical Salts and Co-crystals - Johan Wouters 2011-11-04

From crystal structure prediction to totally empirical screening, the quest for new crystal forms has become one of the most challenging issues in the solid state science and particularly in the pharmaceutical world. In this context, multi-component crystalline materials like co-

crystals have received renewed interest as they offer the prospect of optimized physical properties. As illustrated in this first book_ entirely dedicated to this emerging class of pharmaceutical compounds_ the outcome of such endeavours into crystal engineering have demonstrated clear impacts on production, marketing and intellectual property protection of active pharmaceutical ingredients (APIs). Indeed, co-crystallization influences relevant physico-chemical parameters (such as solubility, dissolution rate, chemical stability, melting point, hygroscopicity, à) and often offers solids with properties superior to those of the free drug. Combining both reports of the latest research and comprehensive overviews of basic principles, with contributions from selected experts in both academia and industry, this unique book is an essential reference, ideal for pharmaceutical development scientists and graduate students in pharmaceutical science.

Pharmaceutical Photostability and Stabilization Technology - Joseph T. Piechocki 2006-09-18

Based on a training course developed by Dr. Joseph T. Piechocki and other experts in this field whose contributions appear in this book for two International Meetings on the Photostability of Drugs and Drug Products, this text clarifies the guidelines set by the International Conference on Harmonization (ICH) and provides a comprehensive background

Pharmaceutical Stress Testing - Steven W. Baertschi 2016-04-19

The second edition of *Pharmaceutical Stress Testing: Predicting Drug Degradation* provides a practical and scientific guide to designing, executing and interpreting stress testing studies for drug substance and drug product. This is the only guide available to tackle this subject in-depth. The Second Edition expands coverage from chemical stability into the physical aspects of stress testing, and incorporates the concept of Quality by Design into the stress testing construct / framework. It has been revised and expanded to include chapters on large molecules, such as proteins and antibodies, and it outlines the changes in stress testing that have emerged in recent years. Key features include: A renowned Editorial team and contributions from all major drug companies, reflecting a wealth of experience. 10 new chapters, including Stress

Testing and its relationship to the assessment of potential genotoxic degradants, combination drug therapies, proteins, oligonucleotides, physical changes and alternative dosage forms such as liposomal formulations Updated methodologies for predicting drug stability and degradation pathways Best practice models to follow An expanded Frequently Asked Questions section This is an essential reference book for Pharmaceutical Scientists and those working in Quality Assurance and Drug Development (analytical sciences, formulations, chemical process, project management).

Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms - Linda A. Felton 2016-09-19

Aqueous-based film coating has become routine in the pharmaceutical industry. This process eliminates the use of organic solvents and thus avoids economic, environmental, and toxicological issues related to residual solvents and solvent recovery. Aqueous-based coating, however, is complex and many variables may impact the final product and its performance. This fourth edition of *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms* aims to provide insight into the factors and parameters that should be considered and controlled for the successful development and commercialization of a coated product. The fourth edition has been revised and expanded to reflect the most recent scientific advancements from the literature. The contributing authors explain in detail, using illustrated examples, appropriate steps to solve and ideally avoid formulation, processing, and stability problems and to achieve an optimized dosage form. Trade names and chemical names of commercially marketed coatings are used throughout the text to help familiarize the reader with the various materials available for pharmaceutical applications. This book will be a valuable resource for anyone in the pharmaceutical industry working in the area of aqueous-based film coating.

Proteins and Peptides - Randall J. Mersny 2009-10-19

Addressing the increased use of protein and peptide candidates as treatments for previously untreatable diseases, this comprehensive and progressive source provides the reader with a roadmap to an increased

understanding of issues critical for successfully developing a protein or peptide therapeutic candidate. Proteins and Peptides is

The Syringe Driver - Andrew Dickman 2017-04-27

The syringe driver is a simple and cost-effective method of delivering a continuous subcutaneous infusion (CSCI). A CSCI provides a safe and effective way of drug administration and can be used to maintain symptom control in patients who are no longer able to take oral medication. There have been several developments in this field since the third edition of this highly successful book. The text in this edition has been completely revised, incorporating new treatment options and an extensive list of new compatibility data. This book serves as a valuable reference source, providing comprehensive review of syringe driver use and administration of drugs by CSCI. The first chapter provides an overview of syringe drivers and CSCIs, including a useful array of frequently asked questions. The second chapter provides information about the chemistry of drug incompatibility and degradation. The third chapter comprises revised and referenced information relating to most drugs likely to be administered by CSCI using a syringe driver. The fourth chapter discusses the control of specific symptoms that are often encountered when CSCIs are required. The fifth and final chapter contains an extensive, referenced list of compatibility and stability data relating to drug combinations administered by CSCI.

Preclinical Drug Development - Mark Rogge 2016-04-19

Preclinical Drug Development, Second Edition discusses the broad and complicated realm of preclinical drug development. Topics range from assessment of pharmacology and toxicology to industry trends and regulatory expectations to requirements that support clinical trials. Highlights of the Second Edition include: Pharmacokinetics Modeling and simula

Modern Pharmaceuticals, Two Volume Set - Alexander T. Florence 2016-04-19

This new edition brings you up-to-date on the role of pharmaceuticals and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of

pharmaceuticals and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceuticals helps you stay current

Handbook of Modern Pharmaceutical Analysis - Satinder Ahuja 2010-11-11

Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

International Pharmaceutical Product Registration, Second Edition - Anthony C. Cartwright 2016-04-19

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.

Drug Stereochemistry - Krzysztof Jozwiak 2012-04-23

Drug Stereochemistry: Analytical Methods and Pharmacology, Third Edition covers all aspects of chiral drugs from academic, governmental, industrial, and clinical perspectives, reflecting the many advances in techniques and methodology. Topics include: The use of enzymes in the synthesis and resolution of enantiometrically pure compounds in drug discovery How stereochemistry impacts decisions made in the absorption, distribution, metabolism, excretion, and toxicity (ADMET) stages of drug discovery Pharmacokinetics and pharmacodynamics and the issues faced during the final stages of the drug development process The impact of the International Conference on Harmonisation (ICH) on the use of single isomer drugs Chiral switches The concept of molecular chiral recognition and how it affects the separation and behavior of stereochemically pure drugs Patent issues surrounding chiral switches and the marketing of single enantiomer switches The book provides a solid background on stereochemistry, from its early history, including an overview of terms and concepts, to the current drug development process, legal and regulatory issues, and the new stereoisomeric drugs. It is a one-stop reference for pharmaceutical scientists and chemists working with chiral drug molecules.

Dosage Form Design Parameters - 2018-07-25

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, preformulation 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

Modern Pharmaceutics Volume 1 - Alexander T. Florence 2009-05-28

With over 100 illustrations, Volume 1 addresses the core disciplines of pharmaceutics (absorption, PK, excipients, tablet dosage forms, and packaging), and explores the challenges and paradigms of pharmaceutics. 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 Stability Testing in Pharmaceutical Development - Kim Huynh-Ba 2008-11-16

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Handbook of Bioequivalence Testing - Sarfaraz K. Niazi 2014-10-29
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

Good Laboratory Practice Regulations, Revised and Expanded - Sandy Weinberg 2002-11-06
Fully updated and revised to include the latest information since publication of the first edition in 1989, the Second Edition of this highly

praised reference covers all aspects of the Food and Drug Administration's (FDA) Good Laboratory Practice (GLP) regulations and techniques for implementation. The book details specific standards and general g