Membrane Electrodes In Drug Substances Analysis

Development and Validation of Analytical Methods **Specification of Drug Substances and Products** *Profiles of Drug Substances, Excipients and Related Methodology* **Analytical Profiles of Drug Substances and Excipients** *Prof. of Drug Substances, Excipients and Related Methodology* **Membrane Electrodes in Drug-Substances Analysis** Profiles of Drug Substances, Excipients, and Related Methodology *Analytical Profiles of Drug Substances* **Profiles of Drug Substances, Excipients and Related Methodology** ICH Quality Guidelines Formulation and Analytical Development for Low-Dose Oral Drug Products Drug Stability for Pharmaceutical Scientists Generic Drug Product Development *Stability of Drugs and Dosage Forms* Supercritical Fluid Technology for Drug Product Development Quality Management and Quality Control **Polymorphism in the Pharmaceutical Industry Sterile Drug Products** FDA Approved Animal Drug Products **Forensic Chemistry of Substance Misuse** Pharmaceutical Quality by Design Biosimilar Drug Product Development **Analysis of Drug Impurities Long Acting Animal Health Drug Products Profiles of Drug Substances, Excipients and Related Methodology** *Bioactive Natural Products Solubility in Pharmaceutical Chemistry* **Pharmaceutical Inhalation Aerosol Technology, Second Edition Botanical Drug Products Drugs and the FDA Analytical Profiles of Drug Substances and Excipients Profiles of Drug Substances, Excipients and Related Methodology, Volume 32C.**

Organic Chemistry of Drug Degradation *Stability of Drugs and Dosage Forms Orphan Drugs and Rare Diseases* **Chemical Engineering in the Pharmaceutical Industry** *Developing Drug Products in an Aging Society* **Biological Drug Products Photostability Of Drugs And Drug Formulations FDA Bioequivalence Standards**

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FDA Bioequivalence Standards Jun 28 2019 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.

Biological Drug Products Aug 30 2019 Tested and proven solutions to the challenges of biological drug product development Biological drug products play a central role in combating human diseases; however, developing new successful biological drugs presents many challenges, including labor intensive production processes, tighter regulatory controls, and increased market competition. This book reviews the current state of the science, offering readers a single resource that sets forth the fundamentals as well as tested and proven development strategies for biological drugs. Moreover, the book prepares readers for the challenges that typically arise during drug development, offering straightforward solutions to improve their ability to pass through all the regulatory hurdles and deliver new drug products to the market. Biological Drug Products begins with general considerations for the development of any biological drug product and then explores the strategies and challenges involved in the development of specific types of biologics. Divided into five parts, the book examines: Part 1: General Aspects Part 2: Proteins and Peptides Part 3: Vaccines Part 4: Novel Biologics Part 5: Product Administration/Delivery Each chapter has been prepared by one or more leading experts in biological drug development. Contributions are based on a

comprehensive review and analysis of the current literature as well as the authors' first-hand experience developing and testing new drugs. References at the end of each chapter serve as a gateway to original research papers and reviews in the field. By incorporating lessons learned and future directions for research, Biological Drug Products enables pharmaceutical scientists and students to improve their success rate in developing new biologics to treat a broad range of human diseases.

Botanical Drug Products Jun 08 2020 Botanicals, which have been part of human food and medicine for thousands of years, are perceived as being safer than synthetic pharmaceuticals. The global botanical drug market was expected to reach $26.6 billion by 2017. In terms of FDA regulations, botanical drugs are no different from non-botanical products, having to meet the safety and effectiveness standards of a new drug in accordance. This book comprises a complete start-to-end process from drug-idea conception, to drug development process. Key Features: Provides a complete compendium for botanical drug products Describes what BDP is and how it differs from Pharma, Biopharma, and Nutraceuticals Compiles all critical regulatory steps in a variety of countries Discusses clinical trial management for BDP development and how it differs from conventional chemical-based drugs and biopharmaceutics

Sterile Drug Products May 20 2021 Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products. This book is based on the courses he has delivered for over three decades, to over 3000 participants, and is intended to remain relevant for the indefinite future even as new technologies

and new applications of old technologies become common. This is an ideal reference book for those working directly and indirectly with sterile dosage forms, be it product development (formulation, package, process, analytical), manufacturing, quality control, quality assurance, regulatory, purchasing, or project management. This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools, providing basic knowledge and principles in four main areas of parenteral science and technology: Product development, including formulation, packaging, and process development. Manufacturing, including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control. Quality and regulatory, including the application of good manufacturing practice regulations, aseptic processing guidelines, and unique quality control testing methods for the sterile dosage form Clinical aspects, including administration, potential hazards, and biopharmaceutics of sterile products in a clinical setting.

Analytical Profiles of Drug Substances and Excipients Aug 03 2022 Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Edited by the Associate Director of Analytical Research and Development for the AmericanAssociation of Pharmaceutical Scientists, Analytical Profiles of Drug Substances and Excipients brings this information together into one source. The scope of the series has recently been expanded to include profiles of excipient materials.

Pharmaceutical Quality by Design Feb 14 2021 A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach

outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

FDA Approved Animal Drug Products Apr 18 2021

Prof. of Drug Substances, Excipients and Related Methodology Jul 02 2022 Profiles of Drug Substances, Excipients, and Related Methodology, Volume 46 contains comprehensive profiles of

five drug compounds: Darunavir, Bisoprolol, Betaxolol, Rabeprazole and Irbesartan. In addition, the work contains a chapter reviewing Bioassay Methods and Their Applications in Herbal Drug Research. The comprehensive reviews in the book cover all aspects of drug development and the formulation of drugs, helping readers understand how the drug development community remains essential to all phases of pharmaceutical development. In addition, this work answers why such profiles are of immeasurable importance to workers in the field. The scope of the Profiles series encompasses review articles and database compilations that fall within one or more of the following five broad categories: Physical Profiles of Drug Substances and Excipients, Analytical Profiles of Drug Substances and Excipients, ADME Profiles of Drug Substances and Excipients, Methodology Related to the Characterization of Drug Substances and Excipients, and Methods of Chemical Synthesis. Contains contributions from leading authorities Presents an excellent overview on the physical, chemical and biomedical properties of some regularly prescribed drugs Includes a cumulative index in each volume

Analytical Profiles of Drug Substances Mar 30 2022

Pharmaceutical Inhalation Aerosol Technology, Second Edition Jul 10 2020 This thoroughly revised and expanded reference provides authoritative discussions on the physiologic, pharmacologic, metabolic, molecular, cellular and physicochemical factors, influencing the efficacy and utilization of pharmaceutical aerosol. It analyzes the latest science and developments in the generation, administration and characterization of these compounds, showcasing current clinical applications, the efficiency and limitations of major aerosol products and emerging aerosol therapies impacting the field.

Formulation and Analytical Development for Low-Dose Oral Drug Products Dec 27 2021 There are

unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

Stability of Drugs and Dosage Forms Sep 23 2021 Drug products are complex mixtures of drugs and excipients and, as such, their chemical and physical stability kinetics are complex. This book discusses the stability of these dosage forms with preformulation studies through to the studies on the final products. The book is intended for graduate students, researchers and professionals in the field of Pharmaceutics and Pharmaceutical Chemistry.

Membrane Electrodes in Drug-Substances Analysis Jun 01 2022 Membrane Electrodes in Drug-Substances Analysis discusses the analytical control of drugs using ion-selective membrane electrodes. This book is divided into three parts, comprised of 18 chapters organized according to the topics they cover. The first part covers the general aspects of membrane electrodes, which includes topics such as theoretical considerations and the basic characteristics of membrane electrodes. Part II deals with the general methods of analysis using membrane electrodes, and Part III tackles the determination of drug-substances. This book will be of great use to researchers and professionals engaged in drug research.

Drugs and the FDA May 08 2020 How the FDA was shaped by public health crises and patient

advocacy, told against a background of the contentious hearings on the breast cancer drug Avastin. Food and Drug Administration approval for COVID-19 vaccines and the controversial Alzheimer's drug Aduhelm made headlines, but few of us know much about how the agency does its work. Why is the FDA the ultimate US authority on a drug's safety and efficacy? In Drugs and the FDA, Mikkael Sekeres—a leading oncologist and former chair of the FDA's cancer drug advisory committee—tells the story of how the FDA became the most trusted regulatory agency in the world. It took a series of tragedies and health crises, as well as patient advocacy, for the government to take responsibility for ensuring the efficacy and safety of drugs and medical devices. Before the FDA existed, drug makers could hawk any potion, claim treatment of any ailment, and make any promise on a label. But then, throughout the twentieth century, the government was forced to take action when children were poisoned by contaminated diphtheria and smallpox vaccines, an early antibiotic contained antifreeze, a drug prescribed for morning sickness in pregnancy caused babies to be born disfigured, and access to AIDS drugs was limited to a few clinical trials while thousands died. Sekeres describes all these events against the backdrop of the contentious 2011 hearings on the breast cancer drug Avastin, in which he participated as a panel member. The Avastin hearings, he says, put to the test a century of the FDA's evolution, demonstrating how its system of checks and balances works—or doesn't work.

ICH Quality Guidelines Jan 28 2022 Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the

dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

Profiles of Drug Substances, Excipients and Related Methodology Sep 04 2022 Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Presents comprehensive reviews covering all aspects of drug development and formulation of drugs Profiles creatine monohydrate and fexofenadine hydrochloride, as well as five others Meets the information needs of the drug development community

Specification of Drug Substances and Products Oct 05 2022 Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for

new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction

Supercritical Fluid Technology for Drug Product Development Aug 23 2021 Interconnecting the fundamentals of supercritical fluid (SCF) technologies, their current and anticipated utility in drug delivery, and process engineering advances from related methodological domains and pharmaceutical applications, this volume unlocks the potential of supercritical fluids to further the development of improved pharmaceutical products-from drug powders for respiratory delivery to drug delivery systems for controlled release.

Profiles of Drug Substances, Excipients and Related Methodology, Volume 32C. Mar 06 2020

Quality Management and Quality Control Jul 22 2021 Quality management (QM) practices are the

basis for the successful implementation and maintenance of any QM system. Quality control (QC) is identified as a QM component. Therefore, QM effectiveness is dependent on the QC strategy. QC practice is more or less complex depending on the type of production. The book is focused on new trends and developments in QM and QC in several types of industries from a worldwide perspective. Its content has been organized into two sections and seven chapters written by well-recognized researchers worldwide. Several approaches are debated based on sample traceability, analytical method validation, required parameters, class of exponential regression-type estimators of the population means, determination of impurities, viewpoints, and case studies.

Profiles of Drug Substances, Excipients and Related Methodology Oct 13 2020 Whilst following in the footsteps of previous volumes by presenting comprehensive reviews of drug substances and additional materials, this title also heralds a significant expansion of the scope of the series. Traditional contributions will now also be augmented by publication of critical review chapters that summarize information related to the characterization of drug substances and excipients. This change is required to better meet the needs of the pharmaceutical communtiy and to allow the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series will encompass review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. * Presents comprehensive reviews covering all aspects of drug development and formulation of drugs * Now encompassing critical

review chapters * Meets the information needs of the drug development community

Long Acting Animal Health Drug Products Nov 13 2020 Long acting veterinary formulations play a significant role in animal health, production and reproduction within the animal health industry. Such technologies offer beneficial advantages to the veterinarian, farmer and pet owner. These advantages have resulted in them growing in popularity in recent years. The pharmaceutical scientist is faced with many challenges when innovating new products in this demanding field of controlled release. This book provides the reader with a comprehensive guide on the theories, applications, and challenges associated with the design and development of long acting veterinary formulations. The authoritative chapters of the book are written by some of the leading experts in the field. The book covers a wide scope of areas including the market influences, preformulation, biopharmaceutics, in vitro drug release testing and specification setting to name but a few. It also provides a detailed overview of the major technological advances made in this area. As a result this book covers everything a formulation scientist in industry or academia, or a student needs to know about this unique drug delivery field to advance health, production and reproduction treatment options and benefits for animals worldwide.

Developing Drug Products in an Aging Society Oct 01 2019 This book aims to address the major aspects of future drug product development and therapy for older adults, giving practical guidance for the rational product and clinical development and prescribing of drug products to this ever growing segment of the population. With authors coming from key “aging” markets such as Europe, the USA, China and Japan, the book will provide valuable information for students, scientists, regulators, practitioners, and other healthcare professionals from academia, industry and regulatory bodies.

Orphan Drugs and Rare Diseases Dec 03 2019 This book provides an up-to-date monograph on the drug discovery and regulatory elements of therapuetics used to treat rare or orphan diseases.

Profiles of Drug Substances, Excipients and Related Methodology Feb 26 2022 Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Contributions from leading authorities Informs and updates on all the latest developments in the field

Forensic Chemistry of Substance Misuse Mar 18 2021 This book builds on an earlier publication by the same author: The Misuse of Drugs Act: A Guide for Forensic Scientists. It provides a chemical background to the domestic and international controls on drugs of abuse and related substances, and includes coverage of 'designer drugs' and generic/analogue controls from UK, USA and New Zealand perspectives. More general chapters cover recent history of the drug classification debate, and a proposal for consolidating a wide range of legal controls on chemical substances. This unique book will be appeal to a general readership. Forensic scientists, researchers, teachers, postgraduate

and graduate students will all find this book an exceptional point of reference.
Stability of Drugs and Dosage Forms Jan 04 2020 Drug products are complex mixtures of drugs and excipients and, as such, their chemical and physical stability kinetics are complex. This book discusses the stability of these dosage forms with preformulation studies through to the studies on the final products. The book is intended for graduate students, researchers and professionals in the field of Pharmaceutics and Pharmaceutical Chemistry.
Profiles of Drug Substances, Excipients, and Related Methodology Apr 30 2022 Profiles of Drug Substances, Excipients, and Related Methodology, Volume 47 covers all aspects of drug development and formulation of drugs, meeting the information needs of the drug development community that are essential to all phases of pharmaceutical development. This updated release includes comprehensive profiles of five drug compounds: Vinpocetine; Loratadine; Ticagrelor; Lodenafil; Danazol. The volume also contains a chapter reviewing “Application of Chemometrics using direct Spectroscopic methods as a QC tool in Pharmaceutical Industry and their Validation. Contains contributions from leading authorities Presents an excellent overview of the physical, chemical and biomedical properties of regularly prescribed drugs Contains a cumulative index for easy access to information
Analysis of Drug Impurities Dec 15 2020 A key component of the overall quality of a pharmaceutical is control of impurities, as their presence, even in small amounts, may affect drug safety and efficacy. The identification and quantification of impurities to acceptable standards presents a significant challenge to the analytical chemist. Analytical science is developing rapidly and provides increasing opportunity to identify the structure, and therefore the origin and safety implications of these impurities, and the challenges of their measurement drives the development of

modern quantitative methods. Written for both practicing and student analytical chemists, Analysis of Drug Impurities provides a detailed overview of the challenges and the techniques available to permit accurate identification and quantification of drug impurities.

Organic Chemistry of Drug Degradation Feb 03 2020 The vast majority of drugs are organic molecular entities. A clear understanding of the organic chemistry of drug degradation is essential to maintaining the stability, efficacy, and safety of a drug product throughout its shelf-life. During analytical method development, stability testing, and pharmaceutical manufacturing troubleshooting activities, one of the frequently occurring and usually challenging events would be the identification of drug degradants and understanding of drug degradation mechanisms and pathways. This book is written by a veteran of the pharmaceutical industry who has first-hand experience in drug design and development, drug degradation mechanism studies, analytical development, and manufacturing process troubleshooting and improvement. The author discusses various degradation pathways with an emphasis on the mechanisms of the underlying organic chemistry, which should aid greatly in the efforts of degradant identification, formulation development, analytical development, and manufacturing process improvement. Organic reactions that are significant in drug degradation will first be reviewed and then illustrated by examples of drug degradation reported in the literature. The author brings the book to a close with a final chapter dedicated to the strategy for rapid elucidation of drug degradants with regard to the current regulatory requirements and guidelines. One chapter that should be given special attention is Chapter 3, Oxidative Degradation. Oxidative degradation is one of the most common degradation pathways but perhaps the most complex one. This chapter employs more than sixty drug degradation case studies with in-depth discussion in regard to their unique degradation pathways. With the increasing regulatory requirements on the

quality and safety of pharmaceutical products, in particular with regard to drug impurities and degradants, the book will be an invaluable resource for pharmaceutical and analytical scientists who engage in formulation development, analytical development, stability studies, degradant identification, and support of manufacturing process improvement. In addition, it will also be helpful to scientists engaged in drug discovery and development as well as in drug metabolism studies.
Biosimilar Drug Product Development Jan 16 2021 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.
Photostability Of Drugs And Drug Formulations Jul 30 2019 This text discusses various aspects of the combination of drugs and light. Degradation processes, stabilization of photolabile drug substances within formulations, benefits from the combination of drugs and light, and testing of drug photoreactivity, are some of the topics discussed.
Polymorphism in the Pharmaceutical Industry Jun 20 2021 "Polymorphism in the Pharmaceutical Industry - Solid Form and Drug Development" highlights the relevance of polymorphism in modern pharmaceutical chemistry, with a focus on quality by design (QbD) concepts. It covers all important issues by way of case studies, ranging from properties and crystallization, via thermodynamics, analytics and theoretical modelling right up to patent issues. As such, the book underscores the importance of solid-state chemistry within chemical and pharmaceutical development. It emphasizes why solid-state issues are important, the approaches

needed to avoid problems and the opportunities offered by solid-state properties. The authors include true polymorphs as well as solvates and hydrates, while providing information on physicochemical properties, crystallization thermodynamics, quantum-mechanical modelling, and up-scaling. Important analytical tools to characterize solid-state forms and to quantify mixtures are summarized, and case studies on solid-state development processes in industry are also provided. Written by acknowledged experts in the field, this is a high-quality reference for researchers, project managers and quality assurance managers in pharmaceutical, agrochemical and fine chemical companies as well as for academics and newcomers to organic solid-state chemistry.
Development and Validation of Analytical Methods Nov 06 2022 The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation.

Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Drug Stability for Pharmaceutical Scientists Nov 25 2021 Drug Stability for Pharmaceutical Scientists is a clear and easy-to-follow guide on drug degradation in pharmaceutical formulation. This book features valuable content on both aqueous and solid drug solutions, the stability of

proteins and peptides, acid-base catalyzed and solvent catalyzed reactions, how drug formulation can influence drug stability, the influence of external factors on reaction rates and much more. Full of examples of real-life formulation problems and step-by-step calculations, this book is the ideal resource for graduate students, as well as scientists in the pharmaceutical and related industries. Illustrates important theoretical concepts with numerous examples, figures, calculations, learning problems and questions for self-study and retention of material Provides answers and explanations to test your knowledge Enables you to better understand key concepts such as rate and order of reaction, reaction equilibrium, complex reaction mechanisms and more Includes an in-depth discussion of both aqueous and solid drug solutions and contains the latest international regulatory requirements on drug stability

Generic Drug Product Development Oct 25 2021 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 therapeutica

Analytical Profiles of Drug Substances and Excipients Apr 06 2020 Analytical Profiles of Drug Substances and Excipients

Bioactive Natural Products Sep 11 2020 Bioactive natural products are a rich source of novel therapeutics. Thus, the search for bioactive molecules from nature continues to play an important role in fashioning new medicinal agents. This volume, which comprises sixteen chapters written by active researchers and leading experts in natural products chemistry, brings together an overview of current discoveries in this remarkable field. It also provides information on the industrial application

of natural products for medicinal purposes. This book will serve as a valuable resource for researchers to predict promising leads for developing pharmaceuticals to treat various ailments and disease manifestations.

Solubility in Pharmaceutical Chemistry Aug 11 2020 This book describes the physicochemical fundamentals and biomedical principles of drug solubility. Methods to study and predict solubility in silico and in vitro are described and the role of solubility in a medicinal chemistry and pharmaceutical industry context are discussed. Approaches to modify and control solubility of a drug during the manufacturing process and of the pharmaceutical product are essential practical aspects of this book.

Chemical Engineering in the Pharmaceutical Industry Nov 01 2019 A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the

authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.