Handbook Of Stability Testing In Pharmaceutical Development Regulations Methodologies And Best Practices

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Handbook of Pharmaceutical Manufacturing Formulations - Safaraz K. Niazi 2016-04-19

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

Handbook of Pharmaceutical Biotechnology - Jay P Rho 2003-03-31

Stay up to date with changes in the biopharmaceutical products market! With the growth rate of biopharmaceutical products ascending rapidly since the 1980s, the number of biotechnology companies has risen to more than 1200 new businesses in the Unites States alone. This dramatic increase creates a new set of challenges in education, putting demands on teachers and students to keep pace with innovations in terminology and techniques. The Handbook of Pharmaceutical Biotechnology is essential in meeting those challenges. A practical compendium of biotechnology-produced drugs, the Handbook of Pharmaceutical Biotechnology covers general principles of biotechnology and pharmaceuticals, putting usable information in the hands of those who need it most. The book presents descriptions that break down each pharmaceutical product by pharmacology, pharmacokinetics, clinical applications, toxicities, and dosage guidelines. It also reviews prescription products, discussing clinical uses and trials, adverse reactions, and more. Tables, figures, and extensive references add to each comprehensive summary. The Handbook of Pharmaceutical Biotechnology also includes up-to-date information on: monoclonal antibodies (Abciximab, Muromonab-CD3) enzymes and regulators of enzyme activity (Alteplase, clotting factors, Dornase alpha) anticytokines olgonucleotide and gene therapy hematopoietic growth factors (interleukins, interferons, colony stimulating factors, erythropoietin) As the worldwide production and sales of biotechnology-derived pharmaceuticals and diagnostics continues to grow, teachers, students, and clinical pharmacists need to maintain a clear and current understanding of the field. The Handbook of Pharmaceutical Biotechnology presents a thoughtful and thorough guide to keeping pace in this evolving industry.

Handbook of Preformulation - Sarfaraz K. Niazi 2019-03-22

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. Features: Addresses the preformulation studies of three different types of new active entities - chemical, biological, and botanical, which is the latest

established class of active ingredient classified by the FDA Illustrates the activities comprised in preformulation studies and establishes a method of tasking for drug development projects Includes extensive flow charts for characterization decision making Gives extensive theoretical treatment of principles important for testing dissolution, solubility, stability, and solid state characterization Includes over 50% new material

UHMWPE Biomaterials Handbook - Steven M. Kurtz 2009-04-27

UHMWPE Biomaterials Handbook describes the science, development, properties and application of of ultra-high molecular weight polyethylene (UHMWPE) used in artificial joints. This material is currently used in 1.4 million patients around the world every year for use in the hip, knee, upper extremities, and spine. Since the publication of the 1st edition there have been major advances in the development and clinical adoption of highly crosslinked UHMWPE for hip and knee replacement. There has also been a major international effort to introduce Vitamin E stabilized UHMWPE for patients. The accumulated knowledge on these two classes of materials are a key feature of the 2nd edition, along with an additional 19 additional chapters providing coverage of the key engineering aspects (biomechanical and materials science) and clinical/biological performance of UHMWPE, providing a more complete reference for industrial and academic materials specialists, and for surgeons and clinicians who require an understanding of the biomaterials properties of UHMWPE to work successfully on patient applications. The UHMWPE Handbook is the comprehensive reference for professionals, researchers, and clinicians working with biomaterials technologies for joint replacement New to this edition: 19 new chapters keep readers up to date with this fast moving topic, including a new section on UHMWPE biomaterials; highly crosslinked UHMWPE for hip and knee replacement; Vitamin E stabilized UHMWPE for patients; clinical performance, tribology an biologic interaction of UHMWPE State-of-the-art coverage of UHMWPE technology, orthopedic applications, biomaterial characterisation and engineering aspects from recognised leaders in the field

Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2004-04-27

The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloidons, emul

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-04-04

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Occupational Outlook Handbook - United States. Bureau of Labor Statistics 1976

Handbook of Analytical Quality by Design - Sarwar Beg 2021-01-09

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Handbook of LC-MS Bioanalysis - Wenkui Li 2013-09-03

Consolidates the information LC-MS bioanalytical scientistsneed to analyze small molecules and macromolecules The field of bioanalysis has advanced rapidly, propelled by newapproaches for developing bioanalytical methods, new liquidchromatographic (LC) techniques, and new mass spectrometric (MS)instruments. Moreover, there are a host of guidelines andregulations designed to ensure the quality of bioanalyticalresults. Presenting the best practices, experimental protocols, and thelatest understanding of regulations, this book offers acomprehensive review of LC-MS bioanalysis of small molecules andmacromolecules. It not only addresses the needs of bioanalyticalscientists working on routine projects, but also explores advancedand emerging technologies such as high-resolution mass spectrometryand dried blood spot microsampling. Handbook of LC-MS Bioanalysis features contributions froman international team of leading bioanalytical scientists. Theircontributions

reflect a review of the latest findings, practices,and regulations as well as their own firsthand analyticallaboratory experience. The book thoroughly examines: Fundamentals of LC-MS bioanalysis in drug discovery, drugdevelopment, and therapeutic drug monitoring The current understanding of regulations governing LC-MSbioanalysis Best practices and detailed technical instructions for LC-MSbioanalysis method development, validation, and stabilityassessment of analyte(s) of interest Experimental guidelines and protocols for quantitative LC-MSbioanalysis of challenging molecules, including pro-drugs, acylglucuronides, N-oxides, reactive compounds, and photosensitive andautooxidative compounds With its focus on current bioanalytical practice, Handbook ofLC-MS Bioanalysis enables bioanalytical scientists to developand validate robust LC-MS assay methods, all in compliance withcurrent regulations and standards.

Pharmaceutical Stability Testing to Support Global Markets - Kim Huynh-Ba 2009-12-04

The International Conference of Harmonization (ICH) has worked on har- nizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops – the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the world to discuss important topics related to pharmaceutical stability practices. Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v Freedom of our mind is Mother of all inventions.

Accelerated Predictive Stability (APS) - Fenghe Qiu 2018-06-28

Accelerated Predictive Stability (APS): Fundamentals and Pharmaceutical Industry Practices provides coverage of both the fundamental principles and pharmaceutical industry applications of the APS approach. Fundamental chapters explain the scientific basis of the APS approach, while case study chapters from many innovative pharmaceutical companies provide a thorough overview of the current status of APS applications in the pharmaceutical industry. In addition, up-to-date experiences in utilizing APS data for regulatory submissions in many regions and countries highlight the potential of APS in support of registration stability testing for certain regulatory submissions. This book provides high level strategies for the successful implementation of APS in a pharmaceutical company. It offers scientists and regulators a comprehensive resource on how the pharmaceutical industry can enhance their understanding of a product's stability and predict drug expiry more accurately and quickly. Provides a comprehensive, one-stop-shop resource for accelerated predictive stability (APS) Presents the scientific basis of different APS models Includes the applications and utilities of APS that are demonstrated through numerous case studies Covers up-to-date regulatory experience

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).

Handbook of Pharmaceutical Wet Granulation - Ajit S. Narang 2018-08-31

Handbook of Pharmaceutical Wet Granulation: Theory and Practice in a Quality by Design Paradigm offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation, taking a holistic approach by combining introductory principles with practical solutions. Chapters are written by international experts across industry, academic and regulatory settings, and cover a wide spectrum of relevant and contemporary wet granulation topics, techniques and processes. The books' focus on process

analytical technology, quality by design principles, granulation equipment, modeling, scale-up, control and real time release makes it a timely and valuable resource for all those involved in pharmaceutical wet granulation. Discusses fundamentals of theory and current industrial practice in the field of wet granulation, including product and process design and role of material properties in wet granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies (PATs), and product development and scale-up paradigms Written for scientists working within the pharmaceutical industry, as well as academics, regulatory officials and equipment vendors who provide PAT tools and granulation equipment

Micro- and Nanotechnologies-Based Product Development - Neelesh Kumar Mehra 2021-09-06

This book provides comprehensive information of the nanotechnology-based pharmaceutical product development including a diverse range of arenas such as liposomes, nanoparticles, fullerenes, hydrogels, thermally responsive externally activated theranostics (TREAT), hydrogels, microspheres, micro- and nanoemulsions and carbon nanomaterials. It covers the micro- and nanotechnological aspects for pharmaceutical product development with the product development point of view and also covers the industrial aspects, novel technologies, stability studies, validation, safety and toxicity profiles, regulatory perspectives, scale-up technologies and fundamental concept in the development of products. Salient Features: Covers micro- and nanotechnology approaches with current trends with safety and efficacy in product development. Presents an overview of the recent progress of stability testing, reverse engineering, validation and regulatory perspectives as per regulatory requirements. Provides a comprehensive overview of the latest research related to micro- and nanotechnologies including designing, optimisation, validation and scale-up of micro- and nanotechnologies. Is edited by two well-known researchers by contribution of vivid chapters from renowned scientists across the globe in the field of pharmaceutical sciences. Dr. Neelesh Kumar Mehra is working as an Assistant Professor of Pharmaceutics & Biopharmaceutics at the Department of Pharmaceutics, National Institute of Pharmaceutical Education & Research (NIPER), Hyderabad, India. He received 'TEAM AWARD' for successful commercialisation of an ophthalmic suspension product. He has authored more than 60 peer-reviewed publications in highly reputed international journals and more than 10 book chapter contributions. He has filed patents on manufacturing process and composition to improved therapeutic efficacy for topical delivery. He guided PhD and MS students for their dissertations/research projects. He has received numerous outstanding awards including Young Scientist Award and Team Award for his research output. He recently published one edited book, 'Dendrimers in Nanomedicine: Concept, Theory and Regulatory Perspectives', in CRC Press. Currently, he is editing books on nano drug delivery-based products with Elsevier Pvt Ltd. He has rich research and teaching experience in the formulation and development of complex, innovative ophthalmic and injectable biopharmaceutical products including micro- and nanotechnologies for regulated market. Dr. Arvind Gulbake is working as an Assistant Professor at the Faculty of Pharmacy, School of Pharmaceutical & Population Health Informatics, at DIT University, Dehradun, India. He has authored more than 40 peer-reviewed publications in highly reputed international journals, four book chapters and a patent contribution. He has received outstanding awards including Young Scientist Award and BRG Travel Award for his research. He is an assistant editor for IJAP. He guided PhD and MS students for their dissertations/research projects. He has successfully completed extramural project funded by SERB, New Delhi, Government of India. He has more than 12 years of research and teaching experience in the formulation and development of nanopharmaceuticals.

ICH Quality Guidelines - Andrew Teasdale 2017-10-09

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)

Sterile Drug Products - Michael J. Akers 2016-04-19

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.

A Handbook for Sensory and Consumer-Driven New Product Development - Maurice O'Sullivan 2016-09-16

A Handbook for Sensory and Consumer Driven New Product Development explores traditional and well established sensory methods (difference, descriptive and affective) as well as taking a novel approach to product development and the use of new methods and recent innovations. This book investigates the use of these established and new sensory methods, particularly hedonic methods coupled with descriptive methods (traditional and rapid), through multivariate data analytical interfaces in the process of optimizing food and beverage products effectively in a strategically defined manner. The first part of the book covers the sensory methods which are used by sensory scientists and product developers, including established and new and innovative methods. The second section investigates the product development process and how the application of sensory analysis, instrumental methods and multivariate data analysis can improve new product development, including packaging optimization and shelf life. The final section defines the important sensory criteria and modalities of different food and beverage products including Dairy, Meat, Confectionary, Bakery, and Beverage (alcoholic and non-alcoholic), and presents case studies indicating how the methods described in the first two sections have been successfully and innovatively applied to these different foods and beverages. The book is written to be of value to new product development researchers working in large corporations, SMEs (micro, small or medium-sized enterprises) as well as being accessible to the novice starting up their own business. The innovative technologies and methods described are less expensive than some more traditional practices and aim to be quick and effective in assisting products to market. Sensory testing is critical for new product development/optimization, ingredient substitution and devising appropriate packaging and shelf life as well as comparing foods or beverages to competitor's products. Presents novel and effective sensory-based methods for new product development—two related fields that are often covered separately Provides accessible, useful guidance to the new product developer working in a large multi-national food company as well as novices starting up a new business Offers case studies that provide examples of how these methods have been applied to real product development by practitioners in a wide range of organizations Investigates how the application of sensory analysis can improve new product development including packaging optimization

Regulatory Affairs in the Pharmaceutical Industry - Javed Ali 2021-11-14

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance

Handbook of Formulating Dermal Applications - Nava Dayan 2016-12-07

The conceptualization and formulation of skin care products intended for topical use is a multifaceted and evolving area of science. Formulators must account for myriad skin types, emerging opportunities for product development as well as a very temperamental retail market. Originally published as "Apply Topically" in 2013 (now out of print), this reissued detailed and comprehensive handbook offers a practical approach to the formulation chemist's day-to-day endeavors by: Addressing the innumerable challenges facing the chemist both in design and at the bench, such as formulating with/for specific properties; formulation, processing and production techniques; sensory and elegancy; stability and preservation; color cosmetics; sunscreens; Offering valuable guidance to troubleshooting issues regarding ingredient selection and interaction, regulatory concerns that must be addressed early in development, and the extrapolation of preservative systems, fragrances, stability and

texture aids; Exploring the advantages and limitations of raw materials; Addressing scale-up and pilot production process and concerns; Testing and Measurements Methods. The 22 chapters written by industry experts such as Roger L. McMullen, Paul Thau, Hemi Nae, Ada Polla, Howard Epstein, Joseph Albanese, Mark Chandler, Steve Herman, Gary Kelm, Patricia Aikens, and Sam Shefer, along with many others, give the reader and user the ultimate handbook on topical product development.

Protein Formulation and Delivery - Eugene J. McNally 2007-10-26

This title is intended to assist pharmaceutical scientists in the development of stable protein formulations during the early stages of the product development process, providing a comprehensive review of mechanisms and causes of protein instability in formulation development, coverage of accelerated stability testing methods and relevant analytica

Drug Stability for Pharmaceutical Scientists - Thorsteinn Loftsson 2014-01-25

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

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 Antioxidant Methodology - Paul D. Prenzler 2021-10-20

Addressing a number of the controversies on antioxidant testing methods, this book provides guidance on what methods are most appropriate for different situations, how results are interpreted and what can be inferred from the data.

Essential Chemistry for Formulators of Semisolid and Liquid Dosages - Vitthal S. Kulkarni 2015-10-15

A needed resource for pharmaceutical scientists and cosmetic chemists, Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations. The book covers foundational surface/colloid chemistry, which forms the necessary background for making emulsions, suspensions, solutions, and nano drug delivery systems, and the chemistry of mixing, which is critical for further formulation of drug delivery systems into semisolid (gels, creams, lotions, and ointments) or liquid final dosages. Expanding on these foundational principles, this useful guide explores stability testing methods, such as particle size, rheological/viscosity, microscopy, and chemical, and closes with a valuable discussion of regulatory issues. Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations. Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

Statistics In the Pharmaceutical Industry - C. Ralph Buncher 2019-03-07

The growth of the pharmaceutical industry over the past decade is astounding, but the impact of this growth on statistics is somewhat confusing. While software has made analysis easier and more efficient, regulatory bodies now demand deeper and more complex analyses, and pharmacogenetic/genomic studies serve up an entirely new set of challenges. For more than two decades, Statistics in the Pharmaceutical Industry has been the definitive guide to sorting through the challenges in the industry, and this Third Edition continues that tradition. Updated and expanded to reflect the most recent trends and developments in the field, Statistics in the Pharmaceutical Industry, Third Edition presents chapters written by experts from both regulatory agencies and pharmaceutical companies who discuss everything from experimental design to post-marketing studies. This approach sheds light on what regulators consider acceptable methodologies and what methods have proven successful for industrial statisticians. Both new and revised chapters reflect the increasingly global nature of the industry as represented by authors from Japan and Europe, the increasing trend toward non-inferiority/equivalence testing, adaptive design in clinical trials, global harmonization of regulatory standards, and multiple comparison studies. The book also examines the latest considerations in anti-cancer studies. Statistics in the Pharmaceutical Industry, Third Edition

demystifies the approval process by combining regulatory and industrial points of view, making it a must-read for anyone performing statistical analysis at any point in the drug approval process.

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

Preclinical Development Handbook - Shayne Cox Gad 2008-03-21

A clear, straightforward resource to guide you through preclinical drug development Following this book's step-by-step guidance, you can successfully initiate and complete critical phases of preclinical drug development. The book serves as a basic, comprehensive reference to prioritizing and optimizing leads, dose formulation, ADME, pharmacokinetics, modeling, and regulations. This authoritative, easy-to-use resource covers all the issues that need to be considered and provides detailed instructions for current methods and techniques. Each chapter is written by one or more leading experts in the field. These authors, representing the many disciplines involved in preclinical toxicology screening and testing, give you the tools needed to apply an effective multidisciplinary approach. The editor has carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear. Among the key topics covered are: * Modeling and informatics in drug design * Bioanalytical chemistry * Absorption of drugs after oral administration * Transporter interactions in the ADME pathway of drugs * Metabolism kinetics * Mechanisms and consequences of drug-drug interactions Each chapter offers a full exploration of problems that may be encountered and their solutions. The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage. This publication should be readily accessible to all pharmaceutical scientists involved in preclinical testing, enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin.

CMBEBIH 2017 - Almir Badnjevic 2017-03-14

This volume presents the proceedings of the International Conference on Medical and Biological Engineering held from 16 to 18 March 2017 in Sarajevo, Bosnia and Herzegovina. Focusing on the theme of 'Pursuing innovation. Shaping the future', it highlights the latest advancements in Biomedical Engineering and also presents the latest findings, innovative solutions and emerging challenges in this field. Topics include: - Biomedical Signal Processing - Biomedical Imaging and Image Processing - Biosensors and Bioinstrumentation - Bio-Micro/Nano Technologies - Biomaterials - Biomechanics, Robotics and Minimally Invasive Surgery - Cardiovascular, Respiratory and Endocrine Systems Engineering - Neural and Rehabilitation Engineering - Molecular, Cellular and Tissue Engineering - Bioinformatics and Computational Biology - Clinical Engineering and Health Technology Assessment - Health Informatics, E-Health and Telemedicine - Biomedical Engineering Education - Pharmaceutical Engineering

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

Predictive Modeling of Pharmaceutical Unit Operations - Preetanshu Pandey 2016-09-26

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

Polymorphism in the Pharmaceutical Industry - Rolf Hilfiker 2019-01-04

"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.

Developing Solid Oral Dosage Forms - Yihong Qiu 2009-03-10

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

Handbook of Modern Pharmaceutical Analysis - Satinder Ahuja 2001

This book describes the role modern pharmaceutical analysis plays in the development of new drugs. Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug. Coverage includes state-of-the-art topics such as analytics for combinatorial chemistry and high-throughput screening, formulation development, stability studies, international regulatory aspects and documentation, and future technologies that are likely to impact the field. Emphasis is placed on current, easy-to-follow methods that readers can apply in their laboratories. No book has effectively replaced the very popular text, Pharmaceutical Analysis, that was edited in the 1960s by Tak Higuchi. This book will fill that gap with an up-to-date treatment that is both handy and authoritative.

Handbook of Pharmaceutical Analysis - Lena Ohannesian 2001-11-09

Exploring the analysis of pharmaceuticals, including polymorphic forms, this

book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing. It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules. Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and decomposition products using such techniques as mass spectrometry. The book provides more than 300 tables, equations, drawings, and photographs, and convenient, easy-to-use indices, facilitating quick access to each topic.

Handbook of Isolation and Characterization of Impurities in Pharmaceuticals - Satinder Ahuja 2003-06-26

The United States Food and Drug Administration (FDA) and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation (ICH) be isolated and characterized. Identifying process-related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms. When this process is performed at an early stage, there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high-quality drug product. This book, therefore, has been designed to meet the need for a reference text on the complex process of isolation and characterization of process-related (synthesis and formulation) impurities and degradation products to meet critical requlatory requirements. It's objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates, drug substances, and drug products. The book outlines impurity identification processes and will be a key resource document for impurity analysis, isolation/synthesis, and characterization. - Provides valuable information on isolation and characterization of impurities. - Gives a regulatory perspective on the subject. - Describes various considerations involved in meeting regulatory requirements. - Discusses various sources of impurities and degredation products.

Drug Stability and Chemical Kinetics - Muhammad Sajid Hamid Akash 2020-11-01

This book comprehensively reviews drug stability and chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical kinetics, and providing numerous examples in the form of illustrations, tables and calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry and biopharmaceutics.

Pharmaceutical Process Development - A. John Blacker 2011

This book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry by informing them about the breadth of the work carried out in chemical research and development departments. It is also of great value to academics wishing to advise students on the merits of careers in chemical development over discovery.

Handbook of Pharmaceutical Analysis by HPLC - Satinder Ahuja 2005-02-09

High pressure liquid chromatography–frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, handbook for pharmaceuticals, medical devices, and biologics -

Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics - Carmen Medina 2003-12-09

This text lists the necessary steps for meeting compliance requirements during the drug development process. It presents comprehensive approaches for validating analytical methods for pharmaceutical applications.

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-03-21

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.