Filtration And Purification In The Biopharmaceutical Industry Second Edition Drugs And The Pharmaceutical Sciences

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Filtration and Purification in the Biopharmaceutical Industry - Maik J. Jornitz 2007-11-28

Filtration and Purification in the Biopharmaceutical Industry, First Edition greatly expands its focus with extensive new material on the critical role of purification and the significant advances in filtration science and technology. This new edition provides state-of-the-science information on all aspects of filtration and purification, in

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing - Harry Yang 2016-11-30

The premise of Quality by Design (QbD) is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process. This state-of-the-art book provides a single source of information on emerging statistical approaches to QbD and risk-based pharmaceutical development. A comprehensive resource, it combines in-depth explanations of advanced statistical methods with real-life case studies that illustrate practical applications of these methods in QbD implementation.

Filtration and Purification in the Biopharmaceutical Industry, Second Edition - Maik J. Jornitz 2007-11-28

Filtration and Purification in the Biopharmaceutical Industry, First Edition greatly expands its focus with extensive new material on the critical role of purification and the significant advances in filtration science and technology. This new edition provides state-of-the-science information on all aspects of filtration and purification, including the current methods, processes, technologies and equipment, and brings you up-to-date with the latest industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries. An essential, comprehensive, source for all professionals involved with filtration and purification practices and compliance, this text · addresses recent biotechnology-related processes and advanced technologies, such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and medium and buffer filtration · presents detailed updates on the latest FDA and EMEA regulatory requirements involving filtration and purification practices ·

describes current industry quality standards and validation requirements and provides guidance for compliance Audience:

Biomass, Biofuels, Biochemicals - Ram Sarup Singh 2019-01-31

Biomass, Biofuels and Biochemicals: Advances in Enzyme Technology provides state-of-the-art information on the fundamental aspects and current perspectives in enzyme technology to graduate students, postgraduates and researchers working in industry and academia. The book provides information about the use of enzyme technology as an important tool for biotechnological processes, including food, feed, fuels, textiles, paper, energy and environmental applications. The search for improvements in existing enzyme-catalyzed processes dictates the need to update information on various enzyme technologies. The book gives a snapshot of current practice and research in the area of enzyme technology. Includes current and emerging technologies for the development of novel enzyme catalysis Outlines immobilized enzymes and their implications Refers to enzymes as diagnostic tools Includes metabolic engineering principles for improving industrial enzymes

Handbook of Drug Screening - Ramakrishna Seethala 2016-04-19

Building upon the foundation of basics discussed in the previous edition, the Second Edition provides a more in-depth look at the latest methods and technologies of advanced drug screening, an essential function of drug discovery. With extensively updated content and 21 new chapters, this text examines:quality and efficiency of drug target validati

Handbook for Chemical Process Research and Development, Second Edition - Wenyi Zhao 2023-03-21

This fully updated second edition reflects the significant changes in process chemistry since the first edition and includes more common process issues such as safety, cost, robustness, and environmental impact. Some areas have made notable progress such as process safety, stereochemistry, new reagents and reagent surrogates. Forty years ago there were few process research and development activities in the pharmaceutical industry, partly due to the simplicity of drug molecules. With increasing structural complexity especially the introduction of chiral centers into drug molecules and stricter regulations, process R&D has become one of the critical departments for pharmaceutical companies. Features: This unique volume now in its second edition is designed to provide readers with an unprecedented strategy and approach which will help chemists and graduate students develop chemical processes in an efficient manner. Promotes an industrial mindset concerning safety and commercial viability when developing methods. The author discusses development strategies with case studies and experimental procedures. Focuses on mechanism-guided process development which provides readers with practical strategies and approaches. Addresses more common process issues such as safety, cost, robustness, and environmental impact. This book provides a new direction for scientists, researchers, and students in materials science and polymer chemistry who seek to better understand the chemistry behind conducting polymers and improve their performance for use in advanced energy applications.

Pharmaceuticals in the Environment - R. E. Hester 2016

An important reference for researchers in the pharmaceutical industry, environmentalists and policy makers wanting to better understand the impacts of pharmaceuticals on the environment.

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.

Gene Delivery Systems - Yashwant Pathak 2022-07-01

Gene therapy is a technique that modifies a person's genes to treat or cure disease and can be used as an alternative to using drugs or surgery. Here the authors discuss the development of gene therapy today, from the technology involved to gene correction and the advances in genome editing. Several new drug delivery systems are explored for the applications of gene therapy. These are found to be useful in treating chronic illnesses, including cancer and infectious diseases. Key Features: Overview of the development of gene therapy Provides the most up to date information on the development of gene therapy, from the technology involved to gene correction and genome editing Presents CRISPR gene therapy recent trends and applications Discusses siRNA, mRNA, and DNA plasmids A collection of 15 chapters containing recent research, this volume covers the development of gene therapy, the technology involved, clinical applications of siRNA, non-viral vector-based mRNA delivery using nanotechnology, and RNA based vaccines for treating the infectious diseases. It also presents the current application of CRISPR/Cas9 gene-editing technique, an approach that has recently been given the Nobel Prize in Chemistry, 2020.

Generic Drug Product Development - Leon Shargel 2016-04-19

Generic Drug Product Development: Specialty Dosage Forms explores the issues related to providing evidence of pharmaceutical equivalence and bioequivalence for specialty drug products. It describes various scientific approaches and regulatory requirements for manufacturers who need to demonstrate the therapeutic equivalence of generic specialty drug products to brand name alternatives. The contributors discuss measurement of drug product quality and performance, as well as the regulatory and scientific requirements of topical, nasal and inhalation, and transdermal drug delivery products, along with generic biologics and modified release parenteral drug products. The book is essential reading for specialists and researchers in pharmaceutical drug development, regulation, manufacturing, and others in the pharmaceutical sciences.

Development of Biopharmaceutical Parenteral Dosage Forms - Cosimo Prantera 1997-07-25

This up-to-the-minute reference delineates-in a systematic fashion-the appropriate, sequential steps for the formulation of safe, effective, stable, and marketable liquid parenteral biopharmaceutical products-covering fundamentals and essential pathways for each phase as well as its purpose, function, and relation to other stages in the product development process. Written by experts currently involved in state-of-the-art advances in the pharmaceutical drug industry, Development of Biopharmaceutical Parenteral Dosage Forms details biopharmaceuticals that are licensed or undergoing clinical development, including genetically engineered cell and engineered vectors in the fermentation process describes purification and characterization techniques for rDNA therapeutics, discussing several types of unit operations for isolation, purification, and characterization considers preformulation and formulation requirements, such

as physicochemical properties, drug delivery, stability studies programs, deactivation/denaturation routes, selection of compatible excipients, and regulatory compliance elucidates basics of analytical techniques, methods development, separation methods using chromatographic and electrophoretic techniques, and bioactivity methods covering bioassays and immunoassays for quantifying the stability of biological activity shows how to select the appropriate filter for maximizing compatibility and minimizing adsorption and inactivation, examining topics from basic filtration theories to future trends reviews the selection process for compatible elastomeric closures, analyzing physical, chemical, toxicological properties, protein adsorption on elastomeric surfaces, strategies to reduce/eliminate adsorption, and specialized containers for biotechnological applications and more! Furnished with helpful references, tables, and drawings, this practical guide is indispensable for pharmaceutical, medicinal, and protein chemists; molecular biologists; process engineers; purification scientists; biopharmaceutical and pharmaceutical formulators and product developers; quality control, quality assurance, and regulatory compliance personnel; and upper-level undergraduate and graduate students in these disciplines.

Encyclopedia of Pharmaceutical Technology - James Swarbrick 2013-07-01

Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com

Pharmaceuticals in the Environment - Benoit Roig 2010-08-14

About 4000 medical compounds are being used in the drugs applied today. It is estimated that worldwide consumption of active compounds amounts to some 100,000 tons or more per year. Consequently, there is a need to highlight the most important questions and issues related to presence of pharmaceuticals in the environment. Pharmaceuticals in the Environment: current knowledge and need assessment to reduce presence and impact brings together results of previous and on-going EU projects with published data from both governmental sources and scientific literature and manufacturers' data on production and usage of pharmaceuticals. This book puts together the current knowledge and emphasises questions that deserve attention such as: What is the spectrum of most relevant pharmaceutical products (PPs) for the aquatic environment? Which indicators for supporting environmental managers, health authorities? What is the efficiency of urban and industrial sewage treatment plants over a year? What is the fate and behaviour of PPs in sewage treatment plants? If receiving waters are used for potable water supplies, does the presence of these compounds represent a potential hazard to human health? Could we solve some problems by environmental or cleaner technologies? What regulatory approaches, incentives, prevention actions can be implemented in order to lower PPs concentration in the environment? Does a European practical guidance can be developed? Can the impacts of PPs on the environment be reduced through the use of eco-pharmaco-stewardship approaches including the use of clean synthesis, classification and labelling, and better communication of methods of 'good practice'? How can we better monitor the environmental impact of a pharmaceutical once it has received a marketing authorisation?

Manufacturing of Pharmaceutical Proteins - Stefan Behme 2021-12-09

An expert, single-volume overview of the core processes and disciplines of biopharmaceutical production In the newly revised Third Edition of Manufacturing of Pharmaceutical Proteins: From Technology to Economy, renowned chemical engineer Dr. Stefan Behme delivers a

comprehensive text covering all aspects of biopharmaceutical manufacturing, including legal and regulatory considerations, production facility design, quality assurance, supply chain management, emerging market regulations, and cost control. Suitable as both a reference book and a training resource, this book extensively explores the impact of digital transformation on pharmaceutical protein manufacturers and includes a brand-new chapter dedicated to digitalization. The distinguished author provides readers with practical understanding of the terminology and principles driving the various fields involved with biotechnological production, including operations, legal, finance, and IT. He also offers: A thorough introduction to biopharmaceutical production, including value creation, product types, and biological basics Comprehensive explorations of the technology of the manufacturing process and analytics Practical discussions of pharmacology and drug safety, quality assurance, and pharmaceutical law In-depth examinations of pharmaceutical protein production facilities, including facility design and the planning, construction, and commissioning of a manufacturing plant Perfect for biotechnologists working in the pharmaceutical industry, Manufacturing of Pharmaceutical Proteins: From Technology to Economy will also earn a place in the libraries of pharmaceutical engineers seeking a one-stop reference for all aspects of biopharmaceutical production.

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: PharmacokineticsModeling and simula

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

Oral Drug Absorption - Jennifer B. Dressman 2016-04-19

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an

Percutaneous Absorption - Nina Dragićević 2021-07-30

Updating and expanding the scope of topics covered in the previous edition, Percutaneous Absorption: Drugs, Cosmetics, Mechanisms, Methods, Fifth Edition supplies new chapters on topics currently impacting the field including cutaneous metabolism, skin contamination, exposure to protein allergens, in vitro absorption methodology and the percutaneous absorption of chemical mixtures. Complete with studies on the role of the skin as a key portal of entry for chemicals into the body, this book serves as a detailed reference source for recent advances in the field, as well as an experimental guide for laboratory personnel. Key Features: Details in vivo and in vitro methods for measuring absorption, dermal decontamination, mechanisms of transdermal delivery, and the relationship of transepidermal water loss to percutaneous absorption Considers a range of mathematical models, the safety evaluation of cosmetic ingredients, the absorption of hair dyes, nanoparticles for drug delivery, and other novel methods of drug delivery Discusses topics including skin metabolism, the skin reservoir, and the effects

of desquamation on absorption

Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, Third Edition - Linda A. Felton 2008-01-09

Thoroughly updated and expanded, this new Third Edition provides the latest information on dosage, forms, film defects, and polymer characterization. Written by renowned leaders in the field, Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms is easily the most comprehensive book available on the market today. New to the Third Edition: the interaction of drugs with functional polymers the influence of processing parameters on coating quality the stabilization of polymeric film coats plasticizers and their applications in pharmaceutical coatings adhesion of polymeric films to solid substrates basic properties of latex and pseudolatex colloidal dispersions Key topics included: polymer interactions with drugs and excipients physical aging of polymeric films a complete overview and in-depth analysis of recent advances in the field, which includes information on the latest equipment used to apply polymers to a pharmaceutical system illustrated examples explaining the appropriate steps to be taken in order to solve formulation, processing, and stability problems to achieve an optimized dosage form

Process Scale Purification of Antibodies - Uwe Gottschalk 2017-03-02

Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing

Preparing for FDA Pre-Approval Inspections - Martin D. Hynes 2016-04-19

This Second Edition is an essential guide to preparing for FDA pre-approval inspections-taking into account current trends in FDA expectations and inspection activities, such as the GMPs of the 21st Century, quality systems-based approach to inspections, risk-based inspections, quality by design, process analytical technology, design space, etc. Th

Principles of Fermentation Technology - Peter F Stanbury 2016-08-31

The successful structure of the previous edition of Principles of Fermentation Technology has been retained in this third edition, which covers the key component parts of a fermentation process including growth kinetics, strain isolation and improvement, inocula development, fermentation media, fermenter design and operation, product recovery, and the environmental impact of processes. This accurate and accessible third edition recognizes the increased importance of animal cell culture, the impact of the post-genomics era on applied science and the huge contribution that heterologous protein production now makes to the success of the pharmaceutical industry. This title is ideally suited for both newcomers to the industry and established workers as it provides essential and fundamental information on fermentation in a methodical, logical fashion. Stanbury, Whitaker and Hall have integrated the biological and engineering aspects of fermentation to make the content accessible to members of both disciplines with a focus on the practical application of theory. This text collates all the fermentation fundamentals into one concise reference, making it a valuable resource for fermentation scientists, as well as those studying in the field. Retains its successful structure and covers all components of the fermentation process Integrates the biological and engineering aspects of fermentation to discuss the most recent developments and advancements in the field

Written in a style accessible to readers from either a biological or engineering background with each chapter supported by an extensive bibliography

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

Generic Drug Product Development - Isadore Kanfer 2016-04-19

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

Filtration and Purification in the Biopharmaceutical Industry, Third Edition - Maik W. Jornitz 2019-06-26

Since sterile filtration and purification steps are becoming more prevalent and critical within medicinal drug manufacturing, the third edition of Filtration and Purification in the Biopharmaceutical Industry greatly expands its focus with extensive new material on the critical role of purification and advances in filtration science and technology. It provides state-of-the-science information on all aspects of bioprocessing including the current methods, processes, technologies and equipment. It also covers industry standards and regulatory requirements for the pharmaceutical and biopharmaceutical industries. The book is an essential, comprehensive source for all involved in filtration and purification practices, training and compliance. It describes such technologies as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration. Features: Addresses recent biotechnology-related processes and advanced technologies such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration of medium, buffer and end product Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and purification practices, as well as discussions on best practises in filter integrity testing Describes current industry quality standards and validation requirements and provides guidance for compliance, not just from an end-user perspective, but also supplier requirement It discusses the advantages of single-use process technologies and the qualification needs Sterilizing grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs The book has been compilated by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing. Each specific topic has been thoroughly examined by a subject matter expert.

Active Pharmaceutical Ingredients - Stanley Nusim 2016-04-19

To successfully bring an Active Pharmaceutical Ingredient (API) to market, many steps must be

followed to ensure compliance with governmental regulations. Active Pharmaceutical Ingredients is an unparalleled guide to the development, manufacturing, and regulation of the preparation and use of APIs globally. Topics include:Safety, efficacy, and envi

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.

Martin's Physical Pharmacy and Pharmaceutical Sciences - Alfred N. Martin 2011

Martin's Physical Pharmacy and Pharmaceutical Sciences is considered the most comprehensive text available on the application of the physical, chemical and biological principles in the pharmaceutical sciences. It helps students, teachers, researchers, and industrial pharmaceutical scientists use elements of biology, physics, and chemistry in their work and study. Since the first edition was published in 1960, the text has been and continues to be a required text for the core courses of Pharmaceutics, Drug Delivery, and Physical Pharmacy. The Sixth Edition features expanded content on drug delivery, solid oral dosage forms, pharmaceutical polymers and pharmaceutical biotechnology, and updated sections to cover advances in nanotechnology.

Biopharmaceuticals - Gary Walsh 2013-04-29

The latest edition of this highly acclaimed textbook, provides a comprehensive and up-to-date overview of the science and medical applications of biopharmaceutical products. Biopharmaceuticals refers to pharmaceutical substances derived from biological sources, and increasingly, it is synonymous with 'newer' pharmaceutical substances derived from genetic engineering or hybridoma technology. This superbly written review of the important areas of investigation in the field, covers drug production, plus the biochemical and molecular mechanisms of action together with the biotechnology of major biopharmaceutical types on the market or currently under development. There is also additional material reflecting both the technical advances in the area and detailed information on key topics such as the influence of genomics on drug discovery.

Proteins and Peptides - Randall J. Mrsny 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

Parenteral Medications, Fourth Edition - Sandeep Nema 2019-07-19

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a

comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

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

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

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

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.

Disposable Bioprocessing Systems - Sarfaraz K. Niazi 2016-04-19

Written by a researcher with experience designing, establishing, and validating biological manufacturing facilities worldwide, this is the first comprehensive introduction to disposable systems for biological drug manufacturing. It reviews the current state of the industry; tackles questions about safety, costs, regulations, and waste disposal; and guides readers to choose disposable components that meet their needs. This practical manual covers disposable containers, mixing systems, bioreactors,

connectors and transfers, controls and sensors, downstream processing systems, filling and finishing systems, and filters. The author also shares his predictions for the future, calling disposable bioprocessing technology a "game changer."

Aulton's Pharmaceutics - Michael E. Aulton 2013

"Pharmaceutics is the art of pharmaceutical preparations. It encompasses design of drugs, their manufacture and the elimination of micro-organisms from the products. This book encompasses all of these areas."--Provided by publisher.

Drug-Drug Interactions - A. David Rodrigues 2019-01-03

Authored by renowned leaders in the field, this comprehensive volume covers all aspects of drug-drug interactions, including preclinical, clinical, toxicological, and regulatory perspectives.Thoroughly updated, this second edition reflects the significant advances and includes extensive new material on:key interplay between transporters and enzymes

Dermal Absorption and Toxicity Assessment - Michael S. Roberts 2007-12-14

The source Dermal Absorption and Toxicity Assessment supplies a state-of-the-art overview of the dermal absorption process, and is divided into six well organized sections. Written by internationally recognized experts in the field, this Second Edition is a complete revised and updated text, covering the wide range of methods used to assess skin ab

Gene Delivery - Yashwant Pathak 2022-06-29

Gene delivery is a transport of genes of therapeutic values into the chromosomes of the cells or tissues which can be targeted to replace the faulty genes. In last two decades lot of research efforts are dedicated to gene delivery for therapeutic applications. Today gene therapy is promising approach in treatment of genetic diseases including mitochondrial related diseases like blindness, muscular dystrophy, cystic fibrosis, and some cancers. Gene Delivery Systems: Nano Delivery Technologies observes the exploration of nanotechnology for gene therapy and gene delivery. Written by prominent authors in the field, this book covers various aspects of gene delivery including challenges in delivering gene therapy, advances in genome editing, RNA-based gene therapy, Green nanoparticles for oligonucleotide delivery. Additional features include" Provides the most up to date information on the development of gene therapy, from the technology involved to gene correction and genome editing. Includes knowledge of the current application of CRISPR/Cas9 gene-editing technique; an approach that has recently been given the Noble Prize. Examines the development of mRNA vaccines for Covid -19 in challenging pandemic scenario Discusses siRNA, mRNA, and DNA plasmids.