Handbook Of Bioequivalence Testing Second Edition Drugs And The Pharmaceutical Sciences By Sarfaraz K Niazi 2014 10 29

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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.
Pharmaceutical Extrusion Technology - Isaac Ghebre-Sellassie 2018-03-05
The first edition of Pharmaceutical Extrusion Technology, published in 2003, was deemed the seminal book on pharmaceutical extrusion. Now it is expanded and improved, just like the usage of extrusion has expanded, improved and evolved into an accepted manufacturing technology to continuously mix active pharmaceutical ingredients with excipients for a myriad of traditional and novel dosage forms. Pharmaceutical Extrusion Technology, Second Edition reflects how this has spawned numerous research activities, in addition to hardware and process advancements. It offers new authors, expanded chapters and contains all the extrusion related technical information necessary for the development, manufacturing, and marketing of pharmaceutical dosage forms. Key Features: Reviews how extrusion has become an accepted technology to continuously mix active pharmaceutical ingredients with excipients Focuses on equipment and process technology Explains various extrusion system configurations as a manufacturing methodology for a variety of dosage forms Presents new opportunities available only via extrusion and future trends Includes contributions of experts from the process and equipment fields
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.
Good Laboratory Practice for Nonclinical Studies - Graham P. Bunn 2022-12-13
The GLP regulations have been enacted since 1978 and are currently under a proposed FDA amendment to revise terminology and accommodate other changes relating to advances in technology related to the industry. This book provides a unique opportunity to access interpretation of the 21CFR58 regulatory requirements from leading industry experts with a vast knowledge and expertise in their fields. The approach used takes the regulations, provides interpretations and references to examples and regulatory actions. Data integrity and the use of electronic systems in compliance with 21CFR11 Electronic Records: Electronic Signatures are also discussed. • Unique volume covering FDA inspections of GLP facilities • Provides a detailed interpretation of GLP Regulations • Presents the latest on electronic data management in GLP • Describes GLP and computer systems validation • Can be referenced repeatedly in supporting daily hands on implementation of the CFR requirements
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
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.
Good Manufacturing Practices for Pharmaceuticals, Seventh Edition - Graham P. Bunn 2019-02-04
This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.
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

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.

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

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex. The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies, along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval—including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs—allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

Biosimilars and Interchangeable Biologics - Sarfaraz K. Niazi 2016-01-05

What’s the Deal with Biosimilars? Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction time in costs and development. Part of a two-volume set that covers varying aspects of biosimilars, Biosimilars and Interchangeable Biologics: Tactical Elements explores the development and manufacturing of biosimilars and targets challenges surrounding the creation of these products. This includes manufacturing, production costs, and intellectual property barriers, particularly in regulated markets (regulatory agencies are still in the process of developing guidelines). It addresses the complexity of biological drugs, and it discusses specific structural elements vital to the functionality, immunogenicity, and safety of biosimilar products. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume provides an overall understanding of the hurdles, difficulties, and practicalities of developing a strong plan. It introduces a step-by-step approach for creating a strategy that helps develop and manufacture a biosimilar product while reducing overall production costs and meeting the requirements of biosimilarity based on analytical and functional, pharmacokinetic, pharmacodynamic (where applicable), and nonclinical toxicology or toxicokinetic similarity (where appropriate) while remaining competitive in the market.

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

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

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

Drug Delivery Nanoparticles Formulation and Characterization - Yashwant Pathak 2016-04-19

Exploring fundamental concepts, Drug Delivery Nanoparticles Formulation and Characterization presents key aspects of nanoparticulate system development for various therapeutic applications and provides advanced methods used to file for regulatory approval.This comprehensive guide features:Process Analytical Techniques (PAT) used in manufacturing Na

Handbook of Pharmaceutical Granulation Technology - Dilip M. Parikh 2021-05-12

This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration, process control, process modelling, scale-up, emerging particle engineering technologies, along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe. Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology. Every pharmaceutical scientist should own a copy of this fourth edition resource. Key Features: Theoretical discussions covering granulation and engineering perspectives. Covers new advances in expert systems, process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies

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

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

Biosimilar Drug Product Development - Laszlo Endrenyi 2017-02-24

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

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

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

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

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

This new edition brings you up-to-date on the role of pharmaceutics and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of pharmaceutics and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceutics helps you stay current

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

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

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

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

The Future of Pharmaceuticals - Sarfaraz K. Niazi 2022-03-01

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

Handbook of Pharmaceutical Manufacturing Formulations, Second Edition - Sarfaraz K. Niazi 2009-09-21

An authoritative and practical guide to the art and science of formulating drugs. With thoroughly revised and expanded content, this Second Edition six-volume set compiles volumes from FDA New Drug Applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of issues concerning drug manufacturing. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this set is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. As the largest reference on pharmaceutical formulations, this handbook also provides guidelines on how to file aNDAs in the shortest possible time, helping pharmaceutical companies to cut costs in the areas of pharmaceutical research and development. Divided conveniently into two parts—regulatory and manufacturing guidelines, and formulations—each volume in the set covers: cGMP compliance pre-approval inspections stability and bioequivalence testing packaging commodity development common difficulties in formulating drugs changes to aNDAs

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

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

Handbook of Drug Metabolism, Third Edition - Paul G. Pearson 2019-05-20

This book continues to be the definitive reference on drug metabolism with an emphasis on new scientific and regulatory developments. It has

been updated based on developments that have occurred in the last 5 years, with new chapters on large molecules disposition, stereo-selectivity in drug metabolism, drug transporters and metabolic activation of drugs. Some chapters have been prepared by new authors who have emerged as subject area experts in the decade that has passed since publication of the first edition.

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

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

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

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

Fundamentals of Modern Bioprocessing - Sarfaraz K. Niazi 2017-07-27

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

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

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

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

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

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

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

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

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

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

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

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

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition - Sarfaraz K. Niazi 2019-12-06

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Five, Over-the-Counter Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this fifth volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author’s

own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines