Development Of A Usp Apparatus 3 Dissolution Method For

Drug Delivery Systems examines the current state of the field within pharmaceutical science and concisely explains the history of drug delivery systems, including key developments. The book translates the physicochemical properties of drugs into drug delivery systems administered via various routes, such as oral, parenteral, transdermal and inhalational. Regulatory and product development topics are also explored. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of drug delivery systems within the pharmaceutical sciences industry and research, as well as in chemical engineering. Each chapter delves into a particular aspect of this fundamental field to cover the principles, methodologies and technologies employed by pharmaceutical scientists. This book provides a comprehensive examination that is suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnologies, and related industries. Provides up-to-date information on how to translate the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various routes, such as oral, parenteral, transdermal and inhalational Contains extensive references and further reading for course and self-study

The worldwide impact of HIV/AIDS is well recognized. This book provides for the first

time a thorough and critical overview of current aspects, recent developments, and trends in the formulation and drug delivery concerning anti-HIV microbicides by leading scientists in the field. Additionally, pertinent regulatory aspects and socioeconomical issues related to the subject are discussed. In the absence of a cure, prophylaxis represents a cornerstone in the battle against infection. One promising strategy comprises the use around the time of sexual intercourse of vaginal/rectal products containing antiviral compounds, termed microbicides. It is now recognized that specific development of drug dosage forms and/or drug delivery systems is an indispensable aspect for the success of microbicides. Different groups strived over the last decade to optimize the biophysical and technological performance of traditional dosage forms (gels, tablets, and suppositories) to fulfill the specificities of microbicides use, without neglecting users' preferences and affordability issues. Moreover, new formulation approaches, such as vaginal rings and films, nanotechnology-based systems, stimuli-sensitive formulations, targeted drug delivery systems, among others have been proposed and are currently undergoing pre-clinical or even clinical testing.

Vols. 7- include "Abstracts" which, beginning with v. 9 form a separately paged section, and from v. 17 on, have separate title pages.

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.

Formulation and Analytical Development for Low-Dose Oral Drug Products

Drug Delivery Systems

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence

Pharmaceutics

A Comprehensive Guide on Biopharmacy and Pharmacokinetics

Natural and Synthetic Biomedical Polymers

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its

role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive

experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Explore the cutting-edge of dissolution testing in an authoritative, one-stop resource In Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond, distinguished pharmaceutical advisor and consultant Dr. Umesh Banakar delivers a comprehensive and up-to-date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development. After discussing the fundamentals of the subject, the included resources go on to explore common testing practices and methods, along with their associated challenges and issues, in the drug development life cycle. Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution, apart from mere quality control. Readers will discover a wide range of topics, including automation, generic and biosimilar drug development, patents, and clinical safety. This volume offers a one-stop resource for information otherwise scattered amongst several different regulatory regimes. It also includes: A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility, dissolution, permeability, and classification systems in drug development In-depth examinations of the mechanics of dissolution, including mathematical models and simulations An elaborate assessment of biophysiologically relevant dissolution testing and IVIVCs, and their unique applications A complete understanding of the methods, requirements, and global regulatory expectations pertaining to dissolution testing of generic

drug products Ideal for drug product development and formulation scientists, quality control and assurance professionals, and regulators, Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence is also the perfect resource for intellectual property assessors.

Polymers are important and attractive biomaterials for researchers and clinical applications due to the ease of tailoring their chemical, physical and biological properties for target devices. Due to this versatility they are rapidly replacing other classes of biomaterials such as ceramics or metals. As a result, the demand for biomedical polymers has grown exponentially and supports a diverse and highly monetized research community. Currently worth $1.2bn in 2009 (up from $650m in 2000), biomedical polymers are expected to achieve a CAGR of 9.8% until 2015, supporting a current research community of approximately 28,000+. Summarizing the main advances in biopolymer development of the last decades, this work systematically covers both the physical science and biomedical engineering of the multidisciplinary field. Coverage extends across synthesis, characterization, design consideration and biomedical applications. The work supports scientists researching the formulation of novel polymers with desirable physical, chemical, biological, biomechanical and degradation properties for specific targeted biomedical applications. Combines chemistry, biology and engineering for expert and appropriate integration of design and engineering of polymeric biomaterials Physical, chemical, biological, biomechanical and degradation properties alongside currently deployed clinical applications of specific biomaterials aids use as single source reference on field. 15+ case studies provides in-depth analysis of currently used polymeric biomaterials, aiding design

considerations for the future

Issues in Biochemistry and Biomaterials / 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Biochemistry and Biomaterials. The editors have built Issues in Biochemistry and Biomaterials: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Biochemistry and Biomaterials in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in Biochemistry and Biomaterials / 2011 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Pharmaceutical Theory and Practice

Aulton's Pharmaceutics E-Book

Design, Synthesis, and Case Studies

Encyclopedia of Analytical Science

Specialty Dosage Forms

Science, Applications, and Beyond

Provides practical guidance on pharmaceutical analysis, written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations, working

processes, and drug development best practices used to maintain the quality and integrity of medicines. With a focus on smaller molecular weight drug substances and products, the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices (GMP) regulations. Concise yet comprehensive chapters contain up-to-date coverage of drug regulations, pharmaceutical analysis methodologies, control strategies, testing development and validation, method transfer, electronic data documentation, and more. Each chapter includes a table of contents, definitions of acronyms, a reference list, and ample tables and figures. Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products, this authoritative resource: Describes the structure, roles, core guidelines, and GMP regulations of the FDA and ICH. Covers the common analytical technologies used in pharmaceutical laboratories, including examples of analytical techniques used for the release and stability testing of drugs. Examines control strategies established from quality systems supported by real-world case studies. Explains the use of dissolution testing for products such as extended-release capsules, aerosols, and inhalers. Discusses good documentation and data reporting practices, stability programs, and the Laboratory Information Management System (LIMS) to maintain compliance. Includes calculations, application examples, and illustrations to assist readers in day-to-day laboratory operations.

Contains practical information and templates to structure internal processes or common Standard Operating Procedures (SOPs). Analytical Testing for the Pharmaceutical GMP Laboratory is a must-have reference for both early-career and experienced pharmaceutical scientists, analytical chemists, pharmacists, and quality control professionals. It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs.

Dissolution testing is routinely used in the pharmaceutical industry to provide in vitro drug release information for drug development and quality control purposes. The USP Testing Apparatus 2 is the most common dissolution testing system for solid dosage forms. Usually, sampling cannulas are used to take samples manually from the dissolution medium. However, the inserted cannula can alter the normal fluid flow within the vessel and produce different dissolution testing results. The hydrodynamic effects introduced by a permanently inserted cannula in a USP Dissolution Testing Apparatus 2 were evaluated by two approaches. Firstly, the dissolution tests were conducted with two dissolution systems, the testing system (with cannula) and the standard system (without cannula), for nine different tablet positions using non-disintegrating salicylic acid calibrator tablets. The dissolution profiles at each tablet location in the two systems were compared using statistical tools. Secondly, Particle Image Velocimetry (PIV) was used to obtain experimentally velocity vector maps and velocity profiles in the vessel for

the two systems and to quantify changes in the velocities on selected horizontal so-surfaces. The results show that the system with the cannula produced higher dissolution profiles than that without the cannula and that the magnitude of the difference between dissolution profiles in the two systems depended on tablet location. However, in most dissolution tests, the changes in dissolution profile due to the cannula were small enough to satisfy the FDA criteria for similarity between dissolution profiles (f1 and f2 values). PIV measurements showed slightly changes in the velocities of the fluid flow in the vessel where the cannula was inserted. The most significant velocity changes were observed closest to the cannula. However, generally the hydrodynamic effect generated by the cannula did not appear to be particularly strong, which was consistent to dissolution test results. It can be concluded that the hydrodynamic effects generated by the inserted cannula are real and observable. Such effects result in slightly mod fications of the fluid flow in the dissolution vessel and in detectable differences in the dissolution profiles, which, although limited, can introduce variations in test results possibly leading to failure of routine dissolution tests.

The essential pharmaceutics textbook One of the world’s best-known texts on pharmaceutics, Aulton's Pharmaceutics offers a complete course in one book for students in all years of undergraduate pharmacy and pharmaceutical sciences degrees. Thoroughly revised, updated and extended by experts in their fields and edited by Professors Kevin Taylor and Michael Aulton, this new edition includes the science of

formulation, pharmaceutical manufacturing and drug delivery. All aspects of pharmaceutics are covered in a clear and readily accessible way and extensively illustrated throughout, providing an essential companion to the entire pharmaceutics curriculum from day one until the end of the course. Fully updated throughout, with the addition of new chapters, to reflect advances in formulation and drug delivery science, pharmaceutical manufacturing and medicines regulation Designed and written for newcomers to the design and manufacture of dosage forms Relevant pharmaceutical science covered throughout Includes the science of formulation and drug delivery Reflects current practices and future applications of formulation and drug delivery science to small drug molecules, biotechnology products and nanomedicines Key points boxes throughout Over 400 online multiple choice questions

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.

Chemical, Biological, and Botanical Drugs, Second Edition

The ADME Encyclopedia

Handbook of Preformulation

Basic Principles and Application to Pharmacy Practice

Poorly Soluble Drugs

International Pharmaceutical Product Registration, Second Edition

ORAL DRUG DELIVERY FOR MODIFIED RELEASE FORMULATIONS Provides pharmaceutical development scientists with a detailed reference guide for the development of MR formulations Oral Drug Delivery for Modified Release Formulations is an up-to-date review of the key aspects of oral absorption from modified-release (MR) dosage forms. This edited volume provides in-depth coverage of the physiological factors that influence drug release and of the design and evaluation of MR formulations. Divided into three sections, the book begins by describing the gastrointestinal tract (GIT) and detailing the conditions and absorption processes

occurring in the GIT that determine a formulation's oral bioavailability. The second section explores the design of modified release formulations, covering early drug substance testing, the biopharmaceutics classification system, an array of formulation technologies that can be used for MR dosage forms, and more. The final section focuses on in vitro, in silico, and in vivo evaluation and regulatory considerations for MR formulations. Topics include biorelevant dissolution testing, preclinical evaluation, and physiologically-based pharmacokinetic modelling (PBPK) of in vivo behaviour. Featuring contributions from leading researchers with expertise in the different aspects of MR formulations, this volume: Provides authoritative coverage of physiology, physicochemical determinants, and in-vitro in-vivo correlation (IVIVC) Explains the different types of MR formulations and defines the key terms used in the field Discusses the present status of MR technologies and identifies current gaps in research Includes a summary of regulatory guidelines from both the US and the EU Shares industrial experiences and perspectives on the evaluation of MR dosage formulations Oral Drug Delivery for Modified Release Formulations is an invaluable reference and guide for researchers, industrial scientists, and graduate students in general areas of drug delivery including pharmaceutics, pharmaceutical sciences, biomedical engineering, polymer and materials science, and chemical and biochemical engineering. Including case studies of macrocyclic marketed drugs and macrocycles in drug

development, this book helps medicinal chemists deal with the synthetic and conceptual challenges of macrocycles in drug discovery efforts. Provides needed background to build a program in macrocycle drug discovery –design criteria, macrocycle profiles, applications, and limitations Features chapters contributed from leading international figures involved in macrocyclic drug discovery efforts Covers design criteria, typical profile of current macrocycles, applications, and limitations

Long acting injections and implants improve therapy, enhance patient compliance, improve dosing convenience, and are the most appropriate formulation choice for drugs that undergo extensive first pass metabolism or that exhibit poor oral bioavailability. An intriguing variety of technologies have been developed to provide long acting injections and implants. Many considerations need to go into the design of these systems in order to translate a concept from the lab bench to actual therapy for a patient. This book surveys and summarizes the field. Topics covered in Long Acting Injections and Implants include the historical development of the field, drugs, diseases and clinical applications for long acting injections and implants, anatomy and physiology for these systems, specific injectable technologies (including lipophilic solutions, aqueous suspensions, microspheres, liposomes, in situ forming depots and self-assembling lipid formulations), specific implantable technologies (including osmotic implants, drug eluting stents and microfabricated systems), peptide, protein and vaccine delivery, sterilization, drug

release testing and regulatory aspects of long acting injections and implants. This volume provides essential information for experienced development professionals but was also written to be useful for scientists just beginning work in the field and for others who need an understanding of long acting injections and implants. This book will also be ideal as a graduate textbook.

This book covers the essentials of drug delivery research and provides a unique forum for scientific experimental methods that are exclusively focused by the in-vitro, ex-vivo, and in-vivo methodologies of drug delivery research and felicitates translational research. The book includes recent and novel approaches in evaluation methods of transdermal, nasal, ocular, oral and intraoral, gastro-retentive, colon-targeted, and brain-targeted drug delivery systems. Providing up to date and comprehensive information, this text is invaluable to students, teachers, scientists, and others employed in the field of drug delivery.

Preclinical Development Handbook

Hydrodynamic Effects of a Cannula in a USP Dissolution Testing Apparatus 2

An Implementation Guide

Characterization of Pharmaceutical Nano- and Microsystems

Oral Drug Delivery for Modified Release Formulations

International Regulatory Requirements for Bioequivalence

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 therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

Focusing on scientific and practical aspects of process scale-up, this resource details the theory and practice of transferring pharmaceutical processes from laboratory scale to the pilot plant and production scale. It covers parenteral and nonparenterel liquids and semi-solids, products derived from biotechnology, dry blending and powder handling, granulation and drying, fluid bed applications, compaction and tableting, and film coating and regulatory requirements for scale-up and postapproval changes. Drawing on the experience of twenty contributing researchers, the book employs dimensional analysis as a unified scientific approach to quantify similar processes on different scales.

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, sample preparations, and data handling

The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

The Design and Manufacture of Medicines

Numerical Simulation of Capsule Dissolution in the Usp Apparatus Ii

ICH Quality Guidelines

Developing Solid Oral Dosage Forms

Biopharmaceutics Applications in Drug Development

Novel Developments in Pharmaceutical and Biomedical Analysis

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume One, Compressed Solid 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 first volume of a six-volume set, compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP 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.

Biocompatibility and Performance of Medical Devices, Second Edition, provides an understanding of the biocompatibility and performance tests for ensuring that biomaterials and medical devices are safe and will perform as expected in the biological environment. Sections cover key concepts and challenges faced in relation to biocompatibility in medical devices, discuss the evaluation and characterization of biocompatibility in medical devices, describe preclinical performance studies for bone, dental and soft tissue implants, and provide information on the regulation of medical devices in the European Union, Japan and China. The book concludes with a review of histopathology principles for biocompatibility and performance studies. Presents diverse insights from experts in government, industry and academia Delivers a comprehensive overview of testing and interpreting medical device performance Expanded to include new information, including sections on managing extractables, accelerating and simplifying medical device development through screening and alternative biocompatibility methods, and quality strategies which fasten device access to market

This authoritative volume explores advances in the techniques used to measure percutaneous penetration of drugs and chemicals to assess bioavailability and bioequivalence and discusses how they have been used in clinical and scientific investigations. Seven comprehensive sections examine topics including in vitro drug release, topical drugs products, clinical studies, and guidelines and workshop reports, among others. The book also describes how targeted transdermal drug delivery and more sophisticated mathematical modelling can aid in understanding the bioavailability of transdermal drugs. The first edition of this book was an important reference guide for researchers working to define the effectiveness and safety of drugs and chemicals that penetrated the skin. This second edition contains cutting-edge advances in the field and is a key resource to those seeking to define the bioavailability and bioequivalence of percutaneously active compounds to improve scientific and clinical investigation and regulation. 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.

Photographic Abstracts

Pharmaceutical Process Scale-Up

Issues in Biochemistry and Biomaterials: 2011 Edition

Applications of Pharmacokinetic Principles in Drug Development

ADME and Biopharmaceutical Properties

Handbook of Pharmaceutical Analysis by HPLC

Learn about the analytical tools used to characterize particulate drug delivery systems with this comprehensive overview Edited by a leading expert in the field, Characterization of Pharmaceutical Nano- and Microsystems provides a complete description of the analytical techniques used to characterize particulate drug systems on the micro- and nanoscale.

The book offers readers a full understanding of the basic physicochemical characteristics, material properties and differences between micro- and nanosystems. It explains how and why greater experience and more reliable measurement techniques are required as particle size shrinks, and the measured phenomena grow weaker. Characterization of Pharmaceutical Nano- and Microsystems deals with a wide variety of topics relevant to chemical and solid-state analysis of drug delivery systems, including drug release, permeation, cell interaction, and safety. It is a complete resource for those interested in the development and manufacture of new medicines, the drug development process, and the translation of those drugs into life-enriching and lifesaving medicines. Characterization of Pharmaceutical Nano- and Microsystems covers all of the following topics: An introduction to the analytical tools applied to determine particle size, morphology, and shape Common chemical approaches to drug system characterization A description of solid-state characterization of drug systems Drug release and permeation studies Toxicity and safety issues The interaction of drug particles with cells Perfect for pharmaceutical chemists and engineers, as well as all other industry professionals and researchers who deal with drug delivery systems on a regular basis, Characterization of Pharmaceutical

Nano- and Microsystems also belongs on bookshelves of interested students and faculty who interact with this topic.

During the last two decades, the pharmaceutical industry has been under pressure to reduce development costs and the time needed to bring drugs to market in order to maximize return on investment and bring treatments to patients sooner. To meet these ends, pharmaceutical scientists working in the differing areas of pharmacy, pharmaceutics, and phar

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

The capsule is the second most common type of drug dosage form, yet detailed research of capsule dissolution in the USP Apparatus II (a paddle

dissolution apparatus that mimics the drug dissolution process in an in vivo environment) is not well reported. In this work, a mathematical model was developed that incorporates both the dissolution of the capsule shell and the slug within the capsule shell. Capsule shell dissolution was modeled with the assumption that the shell undergoes an erosion process only. The capsule slug dissolution model incorporated mass transfer principles, Markov chain theory, and the influence of hydrodynamics on capsules dissolution using computational fluid dynamics (CFD)-predicted velocity profiles. To complete the model, the mass transfer coefficients (determined experimentally and theoretically) were incorporated. The model was validated by statistically comparing the simulated profiles to the experimental data using the similarity factor. In addition, this model can provide insights into the dissolution mechanism where a drug product may either disintegrate or erode during dissolution testing. This capsule slug dissolution model has the potential to reduce substantially the number of time-consuming physical dissolution experiments and maximize the efficiency of process development.

In Vitro Drug Release Testing of Special Dosage Forms

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition

Analytical Testing for the Pharmaceutical GMP Laboratory
Generic Drug Product Development
Drug Delivery and Development of Anti-HIV Microbicides
In Vitro-In Vivo Correlation

This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis- à -vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in

dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.

Pharmaceutics: Basic Principles and Application to Pharmacy Practice is an engaging textbook that covers all aspects of pharmaceutics with emphasis on the basic science and its application to pharmacy practice. Based on curricular guidelines mandated by the American Council for Pharmacy Education (ACPE), this book incorporates laboratory skills by identifying portions of each principle that can be used in a clinical setting. In this way, instructors are able to demonstrate their adherence to ACPE standards and objectives, simply by using this book. Written in a straightforward and student-friendly manner, Pharmaceutics enables students to gain the scientific foundation to understand drug physicochemical properties, practical aspects of dosage forms and drug delivery systems, and the biological applications of drug administration. Key

ideas are illustrated and reinforced through chapter objectives and chapter summaries. A companion website features resources for students and instructors, including videos illustrating difficult processes and procedures as well as practice questions and answers. Instructor resources include Powerpoint slides and a full-color image bank. This book is intended for students in pharmaceutical science programs taking pharmaceutics or biopharmaceutics courses at the undergraduate, graduate and doctoral level. Chapter objectives and chapter summaries illustrate and reinforce key ideas Designed to meet curricular guidelines for pharmaceutics and laboratory skills mandated by the Accreditation Council for Pharmacy Education (ACPE) Companion website features resources for students and instructors, including videos illustrating difficult processes and procedures and practice questions and answers. Instructor resources include Powerpoint slides and a full-color image bank Providing a roadmap from early to late stages of drug development, this book overviews amorphous solid dispersion technology – a leading platform to deliver poorly water soluble drugs, a major hurdle in today's pharmaceutical industry. • Helps readers understand amorphous solid dispersions and apply techniques to particular pharmaceutical systems • Covers physical and chemical properties, screening, scale-up, formulation, drug product manufacture, intellectual property,

and regulatory considerations • Has an appendix with structure and property information for polymers commonly used in drug development and with marketed drugs developed using the amorphous sold dispersion approach • Addresses global regulatory issues including USA regulations, ICH guidelines, and patent concerns around the world

Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal

formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.

Practical Medicinal Chemistry with Macrocycles

Development and Validation of Analytical Methods

Dissolution and Drug Release

Long Acting Injections and Implants

Volume One, Compressed Solid Products

Journal

The third edition of the Encyclopedia of Analytical Science is a definitive collection of articles covering the latest technologies in application areas such as medicine, environmental science, food science and geology. Meticulously organized, clearly written and fully interdisciplinary, the Encyclopedia of Analytical Science provides foundational knowledge across the scope of modern analytical chemistry, linking fundamental topics with the latest

methodologies. Articles will cover three broad areas: analytical techniques (e.g., mass spectrometry, liquid chromatography, atomic spectrometry); areas of application (e.g., forensic, environmental and clinical); and analytes (e.g., arsenic, nucleic acids and polycyclic aromatic hydrocarbons), providing a one-stop resource for analytical scientists. Offers readers a one-stop resource with access to information across the entire scope of modern analytical science Presents articles split into three broad areas: analytical techniques, areas of application and and analytes, creating an ideal resource for students, researchers and professionals Provides concise and accessible information that is ideal for non-specialists and readers from undergraduate levels and higher

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

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

This volume is an important advancement in the application ofpharmacokinetic (PK) and pharmacodynamic (PO) principles to . drug development. The series of topics presented deal with the application of these tools to everyday decisions that a pharmaceutical scientist encounters. The ability to integrate these topics using PK and PO methods has optimized drug development pathways in the clinic. New technologies in the areas of in vitro assays that are more predictive of human absorption and metabolism and advancement in bioanalytical assays are leading the way to minimize drug failures in later, more expensive clinical development programs. of Pharmacokinetics and pharmacodynamics have become an important component understanding the drug action on the body and is becoming increasingly important in drug labeling due to it's potential for predicting drug behavior in populations that may be difficult to study in adequate numbers during drug development. The ability to correlate drug exposure to effect and model it during the drug development

value chain provides valuable insight into optimizing the next steps to derive maximum information from each study. These principles and modeling techniques have resulted in an expanded and integrated view of PK and PO and have led to the expectations that we may be able to optimally design clinical trials and eventually lead us to identifying the optimal therapy for the patient, while minimizing cost and speeding up drug development. There is wide utility for the book both as a text and as a reference.

Pharmaceutical Amorphous Solid Dispersions

In-Vitro and In-Vivo Tools in Drug Delivery Research for Optimum Clinical Outcomes

Biocompatibility and Performance of Medical Devices

Pharmaceutical Product Development

Topical Drug Bioavailability, Bioequivalence, and Penetration

Recent Advances in Analytical Techniques is a series of updates in techniques used in chemical analysis. Each volume presents information about a selection of analytical techniques. Readers will find information about developments in analytical methods such as chromatography, electrochemistry, optical sensor arrays for pharmaceutical and biomedical analysis. Novel Developments in Pharmaceutical and Biomedical Analysis is the second volume of the series and covers the following topics: o Chromatographic assays of solid dosage forms and their drug dissolution

studies o UHPLC method for the estimation of bioactive compounds o HILIC based LC/MS for metabolite analysis o In vitro methods for the evaluation of oxidative stress o Application of vibrational spectroscopy in studies of structural polymorphism of drugs o Electrochemical sensors based on conductive polymers and carbon nanotubes o Optical sensor arrays for pharmaceutical and biomedical analyses o Chemical applications of ionic liquids o New trends in enantioanalysis of pharmaceutical compounds.

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)