A Novel Usp Apparatus 4 Based Release Testing Method For

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.
This adaptation of Bentley's Textbook of Pharmaceutics follows the same goals as those of the previous edition, albeit in a new look. The content of the old edition has been updated and expanded and several new chapters, viz. Complexations, Stability Testing as per ICH Guidelines, Parenteral Formulations, New Drug Delivery Systems and Pilot Plant Manufacturing, have been included, with an intention to make the book more informative for the modern pharmacists. The book has six sections: Section I deals with the physicochemical principles. Two new chapters: Complexations and ICH Guidelines for Stability Testing, have been added to make it more informative. Section II conveys the information regarding pharmaceutical unit operations and processes. Section III describes the area of pharmaceutical practice. Extensive recent updates have been included in many chapters of this section. Two new chapters: Parenteral Formulations and New Drug Delivery Systems, have been added. Section IV contains radioactivity principles and applications. Section V deals with microbiology and animal products. Section VI contains the formulation and packaging aspects of pharmaceuticals. Pilot Plant Manufacturing concepts are added as a new chapter, which may be beneficial to readers to understand the art of designing of a plant from the pilot plant model.
This authoritative guide will serve as the most current source on the design and manufacturing of parenteral dispersed systems-showcasing the utility of dispersed systems in drug delivery, drug targeting, and pharmaceutical engineering.
Molecularly imprinted polymers (MIPs) are an important functional material because of their potential implications in diverse research fields. The materials have been developed for a range of uses including separation, environmental, biomedical and sensor applications. In this book, the chapters are clustered into two main sections: Strategies to be employed when using the affinity materials, and rational design of MIPs for advanced applications. In the first part, the book covers the recent advances in producing MIPs for sample design, preparation and characterizations. In the second part, the chapters demonstrate the importance and novelty of creation of recognition imprinted on the materials and surfaces for a range of microbial detection sensors in the biomedical, environmental and food safety fields as well as sensing human odor and virus monitoring systems. Part 1: Strategies of affinity materials Molecularly imprinted polymers MIP nanomaterials Micro- and nanotraps for solid phase extraction Carbonaceous affinity nanomaterials Fluorescent MIPs MIP-based fiber optic sensors Part 2: Rational design of MIP for advanced applications MIP-based biomedical and environmental sensors Affinity adsorbents for environmental biotechnology MIP in food safety MIP-based virus monitoring MIP-based drug delivery and controlled release Biorecognition imprints on the

biosensor surfaces MIP-based sensing of volatile organic compounds in human body odour MIP-based microcantilever sensor system

Lipid-Based Nanocarriers for Drug Delivery and Diagnosis explores the present state of widely used lipid-based nanoparticulate delivery systems, such as solid lipid nanoparticles (SLN), nanostructured lipid carriers (NLC), nanoliposomes, micelles, nanoemulsions, nanosuspensions and lipid nanotubes. The various types of lipids that can be exploited for drug delivery and their chemical composition and physicochemical characteristics are reviewed in detail, along with their characterization aspects and effects of their dimensions on drug delivery systems behavior in-vitro and in-vivo. The book covers the effective utilization of these lipids based systems for controlled and targeted delivery of potential drugs/genes for enhanced clinical efficacy. Provides the present state of widely used lipid-based nanoparticulate delivery systems Explores how lipid-based nanocarriers improve drug delivery safety Describes the nanoformulation design and the preparation methods of lipid-based nanocarriers

The Chapter Answer Book will provide a balance of both formal requirements of the USP chapter as well as practical advice and consideration in complying with the chapter. The reader will be able to follow a nonsterile product from receipt to preparation in a healthcare facility, addressing core elements of the USP chapter. The standards outlined in this chapter include: Facility design specification Personnel training and core competencies Suggested approaches for documenting competency Work practices to meet requirements and best practices Guidelines, procedures, and compliance requirements for compounding nonsterile preparations Compounding quality nonsterile preparations Beyond use dating guidance and training And much more… Author Patricia Kienle is a known authority on sterile compounding. She currently serves as a member of the USP Compounding Expert Committee and was Chair of the subcommittee and Expert Panel that developed USP as a guide for practical advice and explanation to help ensure compliance with the requirements of USP .

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.

Explore the latest research in biopharmaceutics from leading contributors in the field In Basic Biopharmaceutics, distinguished researcher Hannah Batchelor delivers a comprehensive examination of the tools used within the field of biopharmaceutics and their applications to drug development. This edited volume is an indispensable tool for anyone seeking to better understand the field of biopharmaceutics as it rapidly develops and evolves. Beginning with an expansive introduction to the basics of biopharmaceutics and the context that underpins the field, the included resources go on to discuss how biopharmaceutics are integrated into

product development within the pharmaceutical industry. Explorations of how the regulatory aspects of biopharmaceutics function, as well as the impact of physiology and anatomy on the rate and extent of drug absorption, follow. Readers will find insightful discussions of physiologically based modeling as a valuable asset in the biopharmaceutics toolkit and how to apply the principles of the field to special populations. The book goes on to discuss: Thorough introductions to biopharmaceutics, basic pharmacokinetics, and biopharmaceutics measures Comprehensive explorations of solubility, permeability, and dissolution Practical discussions of the use of biopharmaceutics to inform candidate drug selection and optimization, as well as biopharmaceutics tools for rational formulation design In-depth examinations of biopharmaceutics classification systems and regulatory biopharmaceutics, as well as regulatory biopharmaceutics and the impact of anatomy and physiology Perfect for professionals working in the pharmaceutical and biopharmaceutical industries, Basic Biopharmaceutics is an incisive and up-to-date resource on the practical, pharmaceutical applications of the field.

Gels are used in a large variety of commercial and scientific products from drug delivery systems and food science to biomedical sensors. They also are invaluable in MRI physics research where they mimic biological tissue and in radiotherapy quality assurance where they are used to capture the three dimensional radiation dose distribution. This unique book discusses the state-of-the-art of NMR and MRI techniques in studying the physics and chemistry of gel systems, in their application as MRI phantoms and as three dimensional radiation dosimeters. The first part of the book will cover the fundamental physical concepts of gels and the NMR techniques to study gel systems. The second part is dedicated to the application of gels in the life sciences and in the medical practice to validate radiotherapy and new MRI techniques. Filling the gap in literature, this volume provides the scientific reader with an extensive overview of possible techniques and methods to study the interesting properties and applications of gels. For the MRI researcher and medical physicist, the book will be a valuable resource in using gel phantoms for validating contemporary MRI techniques and radiotherapy treatments.

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

Polymeric Nanomaterials in Nanotherapeutics describes how polymeric nanosensors and nanorobotics are used for biomedical instrumentation, surgery, diagnosis and targeted drug delivery for cancer, pharmacokinetics, monitoring of diabetes and healthcare. Key areas of coverage include drug administration and formulations for targeted delivery and release of

active agents (drug molecules) to non-healthy tissues and cells. The book demonstrates how these are applied to dental work, wound healing, cancer, cardiovascular diseases, neurodegenerative disorders, infectious diseases, chronic inflammatory diseases, metabolic diseases, and more. Methods of administration discussed include oral, dental, topical and transdermal, pulmonary and nasal, ocular, vaginal, and brain drug delivery and targeting. Drug delivery topics treated in several subchapters includes materials for active targeting and cases study of polymeric nanomaterials in clinical trials. The toxicity and regulatory status of therapeutic polymeric nanomaterials are also examined. The book gives a broad perspective on the topic for researchers, postgraduate students and professionals in the biomaterials, biotechnology, and biomedical fields. Shows how the properties of polymeric nanomaterials can be used to create more efficient medical treatments/therapies Demonstrates the potential and range of applications of polymeric nanomaterials in disease prevention, diagnosis, drug development, and for improving treatment outcomes Accurately explains how nanotherapeutics can help in solving problems in the field through the latest technologies and formulations

This detailed volume addresses key issues and subtle nuances involved in developing hydrophilic matrix tablets as an approach to oral controlled release. It brings together information from more than five decades of research and development on hydrophilic matrix tablets and provides perspective on contemporary issues. Twelve comprehensive chapters explore a variety of topics including polymers (hypromellose, natural polysaccharides and polyethylene oxide) and their utilization in hydrophilic matrices, critical interactions impacting tablet performance, in vitro physical and imaging techniques, and microenvironmental pH control and mixed polymer approaches, among others. In one collective volume, Hydrophilic Matrix Tablets for Oral Controlled Release provides a single source of current knowledge, including sections of previously unpublished data. It is an important resource for industrial and academic scientists investigating and developing these oral controlled release formulations.

A core subject in pharmaceutics, physical pharmacy is taught in the initial semesters of B. Pharm. The methodical knowledge of the subject is required, and is essential, to understand the principles pertaining to design and development of drug and drug products. Theory and Practice of Physical Pharmacy is unique as it fulfils the twin requirements of physical pharmacy students: the authentic text on theoretical concepts and its application including illustrative exercises in the form of practicals. Covers all the topics included in various existing syllabi of physical pharmacy Provides an integrated understanding of theory and practical applications associated with physicochemical concepts Explore the latest developments in the field of pharmaceutics Reviews the relevance of physicochemical principles in the design of dosage form Ensures proper recapitulation through sufficient end-of-chapter questions Provides valuable learning tool in the form of multiple choice questions Multiple choice questions section especially useful for GPAT aspirants

Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook: Contains practical, up-to-date guidelines for analytical method validation Summarizes the latest regulatory requirements for all aspects of method validation, even those coming from the USP, but undergoing modifications Covers development, optimization, validation, and transfer of many different types of methods used in the regulatory environment Simplifying the overall process of method development, optimization and validation, the guidelines in the Handbook apply to both small molecules in the conventional pharmaceutical industry, as well as well as the biotech industry.

Due to their good mechanical characteristics in terms of stiffness and strength coupled with mass-saving advantage and other attractive physico-chemical

properties, composite materials are successfully used in medicine and nanotechnology fields. To this end, the chapters composing the book have been divided into the following sections: medicine, dental and pharmaceutical applications; nanocomposites for energy efficiency; characterization and fabrication, all of which provide an invaluable overview of this fascinating subject area. The book presents, in addition, some studies carried out in orthopedic and stomatological applications and others aiming to design and produce new devices using the latest advances in nanotechnology. This wide variety of theoretical, numerical and experimental results can help specialists involved in these disciplines to enhance competitiveness and innovation.

Understand and assess the design, delivery, and efficacy of orally administered drugs A practical guide to understanding oral bioavailability, one of the major hurdles in drug development and delivery, Oral Bioavailability: Basic Principles, Advanced Concepts, and Applications is designed to help chemists, biologists, life science researchers, pharmaceutical scientists, pharmacologists, clinicians, and graduate and students become familiar with the fundamentals and practices of the science of oral bioavailability. The difference in rate and extent between a drug taken orally and the actual amount of a drug reaching the circulatory system, oral bioavailability is an essential parameter for determining the efficacy and adverse effects of new and developing medications, as well as finding an optimal dosing regimen. This book provides a much-needed one-stop resource to help readers better understand and appreciate the many facets and complex problems of oral bioavailability, including the basic barriers to oral bioavailability, the methods used to determine relevant parameters, and the challenges of drug delivery. In addition, this comprehensive book discusses biological and physicochemical methods for improving bioavailability, integrates physicochemistry with physiology and molecular biology, and includes several state-of-the-art technologies and approaches—Caco-2 cell culture model, MDCK, and other related cell culture models—which are used to study the science of oral bioavailability.

Lipid Nanocarriers for Drug Targeting presents recent advances in the area of lipid nanocarriers. The book focuses on cationic lipid nanocarriers, solid lipid nanocarriers, liposomes, thermosensitive vesicles, and cubosomes, with applications in phototherapy, cosmetic and others. As the first book related to lipid nanocarriers and their direct implication in pharmaceutical nanotechnology, this important reference resource is ideal for biomaterials scientists and those working in the medical and pharmaceutical industries that want to learn more on how lipids can be used to create more effective drug delivery systems. Highlights the most commonly used types of lipid nanocarriers and explains how they are applied in pharmacy Shows how lipid nanocarriers are used in different types of treatment, including oral medicine, skin repair and cancer treatment Assesses the pros and cons of using different lipid nanocarriers for different therapies

The aim of this book is to present a range of analytical methods that can be used

in formulation design and development and focus on how these systems can be applied to understand formulation components and the dosage form these build. To effectively design and exploit drug delivery systems, the underlying characteristic of a dosage form must be understood--from the characteristics of the individual formulation components, to how they act and interact within the formulation, and finally, to how this formulation responds in different biological environments. To achieve this, there is a wide range of analytical techniques that can be adopted to understand and elucidate the mechanics of drug delivery and drug formulation. Such methods include e.g. spectroscopic analysis, diffractometric analysis, thermal investigations, surface analytical techniques, particle size analysis, rheological techniques, methods to characterize drug stability and release, and biological analysis in appropriate cell and animal models. Whilst each of these methods can encompass a full research area in their own right, formulation scientists must be able to effectively apply these methods to the delivery system they are considering. The information in this book is designed to support researchers in their ability to fully characterize and analyze a range of delivery systems, using an appropriate selection of analytical techniques. Due to its consideration of regulatory approval, this book will also be suitable for industrial researchers both at early stage up to pre-clinical research.

Poorly Soluble DrugsDissolution and Drug ReleaseCRC Press

Offering the latest information in magnetic nanoparticle (MNP) research, this book builds upon the success of the first volume and provides an updated and comprehensive review, from synthesis, characterization, and biofunctionalization to clinical applications of MNPs, including the diagnosis and treatment of cancers. The book captures some of emerging research area which was not available in the first volume. Good Manufacturing Practices and Commercialization of MNPs are also included. This volume, also written by some of the most qualified experts in the field, incorporates new developments in the literature, and continues to bridge the gaps between the different areas in this field.

This book intends to provide the reader with a comprehensive overview about the state of the art regarding the use of nonsteroidal anti-inflammatory drugs (NSAIDs) in physical and rehabilitation medicine and the study of the pharmacodynamics of existing and newly introduced NSAIDs in the management of pain and inflammation. It will also elaborate and refine already known knowledge on the mechanism(s) of nonsteroidal anti-inflammatory agents. This book may provide additional knowledge about the design and development of new drug delivery systems loaded with NSAIDs potentially useful in the treatment of chronic inflammatory-based diseases following circadian cycle, uses of NSAIDs as a source of medicinal plants, and the adverse effects and drug interactions of the nonsteroidal anti-inflammatory drugs.

Issues in Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive

information about Pharmacology, Pharmacy, Drug Research, and Drug Innovation. The editors have built Issues in Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Pharmacology, Pharmacy, Drug Research, and Drug Innovation 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 Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 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/.

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

The application of drug delivery is a valuable, cost-effective lifecycle management resource. By endowing drugs with new and innovative therapeutic benefits, drug delivery systems extend products' profitable lifecycle, giving pharmaceutical companies competitive and financial advantages, and providing patients with improved medications. Formulation development is now being used to create new dosage forms for existing products, which not only reduces the time and expense involved in new drug development, but also helps with regard to patent protection and bypassing existing patents. Today's culture demands convenience, a major factor determining adherence to drug therapy. Over the past few years, patient convenience-oriented research in the field of drug delivery has yielded a range of innovative drug-delivery options. As a result, various drug-delivery systems, including medicated chewing gums, oral dispersible tablets, medicated lozenges and lollipops, have now hit the market and are very popular. These dosage forms offer a highly convenient way to dose medications, not only for special population groups with swallowing difficulties, such as children and the elderly, but for the general populace as well. This book provides valuable insights into a number of formulation design approaches that are currently being used, or could be used, to provide new benefits from existing drug molecules.

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.

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery

com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

Novel Drug Delivery Systems | Transdermal Drug Delivery Systems | Mucoadhesive Drug Delivery Systems | Targeted Drugdelivery Systems | Regulatory Agencies | Quality Assurance | Good Manufacturing Practices | Validation

The rise of bio- and nano-technology in the last decades has led to the emergence of a new and unique type of medicine known as non-biological complex drugs (NBCDs). This book illustrates the challenges associated with NBCD development, as well as the complexity of assessing the effects of manufacturing changes on innovator and follow-on batches of NBCDs. It also touches upon proven marketing authorization requirements for biosimilars that could be effective in evaluating follow-on NBCDs, including a demonstration of control over the manufacturing process and a need for detailed physico-chemical characterization and (pre)clinical tests. This book is meant to be used for years to come as a standard reference work for the development of NBCDs. Moreover, this book aims to stimulate discussions and further our thinking to ensure that decisions regarding the approval of complex drugs are made with relevant scientific data on the table.

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

analytical quality by design) in the development of specifications, method validation and shelf-life prediction

Organic Materials as Smart Nanocarriers for Drug Delivery presents the latest developments in the area of organic frameworks used in pharmaceutical nanotechnology. An up-to-date overview of organic smart nanocarriers is explored, along with the different types of nanocarriers, including polymeric micelles, cyclodextrins, hydrogels, lipid nanoparticles and nanoemlusions. Written by a diverse range of international academics, this book is a valuable reference for researchers in biomaterials, the pharmaceutical industry, and those who want to learn more about the current applications of organic smart nanocarriers. Explores the most recent molecular- and structure-based applications of organic smart nanocarriers in drug delivery Highlights different smart nanocarriers and assesses their intricate organic structural properties for improving drug delivery Assesses how molecular organic frameworks lead to more effective drug delivery systems

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.

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.

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.

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.

From a review of the previous edition: ‘For all the pharmacy students out there part of your pharmacy degree will be to study formulation design and pharmaceutics. This is the holy grail of pharmaceutical technology books. The text reads well and introduces difficult concepts in a more easy-to-understand way, it is definitely worth the money to help you get through the module, if you’re doing a research project in pharmaceutical design then this would also be an excellent buy...This is essential for passing exams and developing professional competence.’ This is the best known text on pharmaceutics. Its strength lies mainly in being a complete course in one book. Reviewers consistently praise its comprehensiveness and its extremely high quality-quality content. Pharmaceutics is one of the most diverse subject areas in pharmaceutical science and an understanding of it is vital for all pharmacists and scientists involved in converting drugs to medicines that can be safely delivered to a patient. The editorial and author team deliver a tour de force of accessibility, coverage and currency in this new edition of a world-class textbook. Relevant chemistry covered throughout Reflects current and future use of biotechnology products throughout Covers ongoing changes in our understanding of biopharmaceutics, certain areas of drug delivery and the significance of the solid state Includes the science of formulation and drug delivery Designed and written for newcomers to the design of dosage forms Key points boxes throughout Summaries at the end of each chapter Fully updated throughout, with particular focus on delivery of biopharmaceuticals, nanotechnology and nanomedicines, parenteral and ocular drug delivery mechanisms. Now comes with

online access on StudentConsult.