Developing Solid Oral Dosage Forms

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

Method Validation in Pharmaceutical Analysis

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.

FDA Bioequivalence Standards

Explore this comprehensive discussion of the application of physiologically- and physicochemical-based models to guide drug delivery edited by leading experts in the field Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics delivers a thorough discussion of drug delivery options to achieve target profiles and approaches as defined by physical and pharmacokinetic models. The book offers an overview of drug absorption and physiological models, chapters on oral delivery routes with a focus on both PBPK and
multiple dosage form options. It also provides an explanation of the pharmacokinetics of the formulation of drugs delivered by systemic transdermal routes. The distinguished editors have included practical and accessible resources that address the biological and delivery approaches to pulmonary and mucosal delivery of drugs. Emergency care settings are also described, with explorations of the relationship between parenteral infusion profiles and PK/PD. The future of drug delivery is addressed via discussions of virtual experiments to elucidate mechanisms and approaches to drug delivery and personalized medicine. Readers will also benefit from the inclusion of: A thorough introduction to the utility of mathematical models in drug development and delivery An exploration of the techniques and applications of physiologically based models to drug delivery Discussions of oral delivery and pharmacokinetic models and oral site-directed delivery A review of integrated transdermal delivery and pharmacokinetics in development An examination of virtual experiment methods for integrating pharmacokinetic, pharmacodynamic, and drug delivery mechanisms Alternative endpoints to pharmacokinetics for topical delivery Perfect for researchers, industrial scientists, graduate students, and postdoctoral students in the area of pharmaceutical science and engineering, Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics will also earn a place in the libraries of formulators, pharmacokineticists, and clinical pharmacologists.

**Handbook of Preformulation**

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

**European Pharmacopoeia**

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.

**Therapeutic Delivery Solutions**

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.
Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence

Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Second Edition illustrates how to develop high-quality, safe, and effective pharmaceutical products by discussing the latest techniques, tools, and scientific advances in preformulation investigation, formulation, process design, characterization, scale-up, and production operations. This book covers the essential principles of physical pharmacy, biopharmaceutics, and industrial pharmacy, and their application to the research and development process of oral dosage forms. Chapters have been added, combined, deleted, and completely revised as necessary to produce a comprehensive, well-organized, valuable reference for industry professionals and academics engaged in all aspects of the development process. New and important topics include spray drying, amorphous solid dispersion using hot-melt extrusion, modeling and simulation, bioequivalence of complex modified-released dosage forms, biowaivers, and much more. Written and edited by an international team of leading experts with experience and knowledge across industry, academia, and regulatory settings. Includes new chapters covering the pharmaceutical applications of surface phenomenon, predictive biopharmaceutics and pharmacokinetics, the development of formulations for drug discovery support, and much more. Presents new case studies throughout, and a section completely devoted to regulatory aspects, including global product regulation and international perspectives.

ICH Quality Guidelines

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 current trends in HPLC ancillary techniques, sample preparations, and data handling.

In Vitro-In Vivo Correlations

Drug Delivery Trends examines a drift in the pharmaceutical field across the wide range of dosage forms, drug delivery systems (micro and nanoparticulate), at the regulatory front and on new types of therapies in the market. This volume additionally covers the challenges on drug delivery systems in terms of preclinical and current ways of determining quality and the options to solve the challenges associated with this. Most small-medium scale industries and academics struggle with initial regulatory challenges so a detailed discussion on regulatory trend covers the necessary basic understanding of regulatory procedures and provides the required guidance. The series Expectations and Realities of Multifunctional Drug Delivery Systems examines the fabrication, optimization, biological aspects, regulatory and clinical success of wide range of drug delivery carriers. This series reviews multifunctionality and applications of drug delivery systems, industrial trends, regulatory challenges and in vivo success stories. Throughout the volumes discussions on diverse aspects of drug delivery carriers, such as clinical, engineering, and regulatory, facilitate insight sharing across expertise area and form a link for collaborations between industry-academic scientists and clinical researchers. Expectations and Realities of Multifunctional Drug Delivery Systems connects formulation scientists, regulatory experts, engineers, clinical experts and regulatory stake holders. The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems. Encompasses trends in drug delivery systems and selected dosage forms Illustrates regulatory, preclinical and quality principles Contains in-depth investigation of upcoming types of drug delivery systems.

Poorly Soluble Drugs

This comprehensive reference provides an in-depth discussion on state-of-the-art regulatory science in bioequivalence. In sixteen chapters, the volume explores a broad range of topics pertaining to bioequivalence, including its origin and principles, statistical considerations, food effect studies, conditions for waivers of bioequivalence studies, Biopharmaceutics Classification Systems, Biopharmaceutics Drug Disposition Classification System, bioequivalence modeling/simulation and best practices in bioanalysis. It also discusses bioequivalence studies with pharmacodynamic and clinical endpoints as well as bioequivalence approaches for highly variable drugs, narrow therapeutic index drugs, liposomes, locally acting gastrointestinal drug products,
topical products and nasal and inhalation products. FDA Bioequivalence Standards is written by FDA regulatory scientists who develop regulatory policies and conduct regulatory assessment of bioequivalence. As such, both practical case studies and fundamental science are highlighted in these chapters. The book is a valuable resource for scientists who work in the pharmaceutical industry, regulatory agencies and academia as well as undergraduate and graduate students looking to expand their knowledge about bioequivalence standards.

Principles and Applications of Biopharmaceutics and Pharmacokinetics

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 September, 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 company 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 Nottingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. Iain 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 development of in vitro-in vivo relationships for ER products. The original idea went back approximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

In Vitro Drug Release Testing of Special Dosage Forms

Specification of Drug Substances and Products

Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

Drug Delivery Trends

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

Developing Solid Oral Dosage Forms

The rapid development of HPLC instrumentation and technology opens numerous possibilities - and entails new questions. Which column should I choose to obtain best results, which gradient fits to my analytical problem, what are recent and promising trends in detection techniques, what is state of the art regarding LC-MS coupling? All these questions are answered by experts in ten self-contained chapters. Besides these more hardware-related and technical chapters, further related areas of interest are covered: Comparison of recent chromatographic data systems and integration strategies, smart documentation, efficient information search in internet, and tips for a successful FDA inspection. This practical approach offers in a condensed manner recent trends and hints, and will also display the advanced reader mistakes and errors he was not aware of so far.

Applied Biopharmaceutics & Pharmacokinetics, Seventh Edition
Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

**Controlled Release Veterinary Drug Delivery**

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.

**Laboratory Control System Operations in a GMP Environment**

**Handbook of Pharmaceutical Manufacturing Formulations, Third Edition**

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

**Drug Delivery Approaches**

A comprehensive textbook on the theoretical and practical applications of biopharmaceutics and pharmacokinetics The field’s leading text for more than three decades Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition provides you with a basic understanding of the principles of biopharmaceutics and pharmacokinetics and applies these principles to drug product development, drug product performance and drug therapy. The revised and updated sixth edition is unique in teaching basic concepts that relate to understanding the complex issues associated with safe and efficacious drug therapy. Written by authors who have both academic and clinical experience, Applied Biopharmaceutics & Pharmacokinetics will help you to: Understand the basic concepts in biopharmaceutics and pharmacokinetics. Use raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, and elimination Critically evaluate biopharmaceutic studies involving drug product equivalency and unequivalency Design and evaluate dosage regimens of drugs, using pharmacokinetic and biopharmaceutic parameters Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them Practical problems and clinical examples with discussions are included in each chapter to help you apply these principles to patient care and drug consultation situations. Chapter Objectives, Chapter Summaries, and Frequently Asked Questions along with additional application questions appear within each chapter to identify and focus on key concepts. Most of the chapters have been revised to reflect our current understanding of drug product performance, bioavailability, bioequivalence, pharmacokinetics, pharmacodynamics, and drug therapy.

**The Pharmacist**
**The Japanese Pharmacopoeia**

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

**Encyclopedia of Pharmaceutical Technology**

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)

**Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition**


**5th International Conference on Biomedical Engineering in Vietnam**

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.

**Pharmaceutical Dissolution Testing**

**Multiparticulate Drug Delivery**

Develop an understanding of FDA and global regulatory agency requirements for Laboratory Control System (LCS) operations In Laboratory Control System Operations in a GMP Environment, readers are given the guidance they need to implement a CGMP compliant Laboratory Control System (LCS) that fits within Global Regulatory guidelines. Using the Quality Systems Approach, regulatory agencies like the FDA and the European Medicine Agency have developed a scheme of systems for auditing pharmaceutical manufacturing facilities which includes evaluating the LCS. In this guide, readers learn the fundamental rules for operating a CGMP compliant
Laboratory Control System. Designed to help leaders meet regulatory standards and operate more efficiently, the text includes chapters that cover Laboratory Equipment Qualification and Calibration, Laboratory Facilities, Method Validation and Method Transfer, Laboratory Computer Systems, Laboratory Investigations as well as Data Governance and Data Integrity. The text also includes chapters related to Laboratory Managerial and Administrative Systems, Laboratory Documentation Practices and Standard Operating Procedures and General Laboratory Compliance Practices. Additionally, a chapter outlining Stability Program operations is included in the text. In addition to these topics, it includes LCS information and tools such as: • End of chapter templates, checklists, and LCS guidance to help you follow the required standards • Electronic versions of each tool so users can use them outside of the text • An in-depth understanding of what is required by the FDA and other globally significant regulatory authorities for GMP compliant systems. For quality assurance professionals working within the pharmaceutical or biopharma industries, this text provides the insight and tools necessary to implement government-defined regulations.

Analytical Method Validation and Instrument Performance Verification

Glucocorticoids—Advances in Research and Application: 2012 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Glucocorticoids. The editors have built Glucocorticoids—Advances in Research and Application: 2012 Edition on the vast information databases of ScholarlyNews™. You can expect the information about Glucocorticoids 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 Glucocorticoids—Advances in Research and Application: 2012 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/.

Handbook of Pharmaceutical Analysis by HPLC

Oral Drug Absorption

Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards. It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter. A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies.

Handbook of Bioequivalence Testing

Many controlled release veterinary drug delivery systems (CRVDDS) are presently in use, and recently there has been a host of new CRVDDS within veterinary medicine. The challenges of this area of drug delivery arise from the unique anatomy and physiology of the target animal, the cost constraints associated with the value of the animal being treated and the extended periods of time that delivery must be sustained for (often measured in months). The purpose of this book is to introduce the reader to the unique opportunities and challenges of the field of CRVDDS and to explain and discuss the basic controlled release principles underlying the development of CRVDDS. Its aim is to provide an overview of many of the areas where CRVDDS have application, and to highlight the opportunities and prospects for controlled release technology in the veterinary field. Controlled Release Veterinary Drug Delivery comprises chapters that provide workers in the field (and those interested in
this area) with information on the design, development and assessment of a variety of CRVDDS. The book contains chapters that describe the relevant animal physiological and anatomical considerations alongside descriptions of current and emerging controlled release delivery systems for a variety of routes for drug delivery, and present overviews on the physical and chemical assessment of veterinary controlled release delivery systems. The veterinary area is abound with opportunities for the development of controlled release drug delivery technologies. It is an area of medicine that is open to the acceptance of novel drug delivery devices, and which readily encompasses the use of novel routes of administration. It is an area of many unmet needs, most of which offer opportunities and unique challenges for the innovative formulation scientist to provide solutions. This book will provide an insight into the biological, clinical and pharmaceutical challenges that face the formulation scientist in this interesting and diverse area of research.

**Formulation and Analytical Development for Low-Dose Oral Drug Products**

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

**Standard Methods for the Examination of Water and Wastewater**

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

**The HPLC Expert**

The landmark textbook on the theoretical and practical applications of biopharmaceutics and pharmacokinetics—now fully updated. Explains how to detect clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them Helps you critically evaluate biopharmaceutical studies involving drug product equivalency and unequivalency Chapters have been revised to reflect the latest clinical perspectives on drug performance, bioavailability, bioequivalence, pharmacokinetics, pharmacodynamics, and drug therapy The field's leading text for more than three decades, Applied Biopharmaceutics & Pharmacokinetics gets you up to speed on the basics of the discipline like no other resource. Practical problems and clinical examples with discussions are integrated within each chapter to help you apply principles to patient care and drug consultation situations. In addition, outstanding pedagogy, including chapter objectives, chapter summaries, and FAQs, plus additional application questions, identify and focus on key concepts. Written by authors who have both academic and clinical experience, Applied Biopharmaceutics & Pharmacokinetics shows you how to use raw data and formulate the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, and elimination. The book also helps you work with pharmacokinetic and biopharmaceutic parameters to design and evaluate dosage regimens of drugs. In the seventh edition of this must-have interactive learning tool, most of the chapters are updated to reflect our current understanding of complex issues associated with safe and efficacious drug therapy.

**The International Pharmacopoeia**

"The signature undertaking of the Twenty-Second Edition was clarifying the QC practices necessary to perform the methods in this manual. Section in Part 1000 were rewritten, and detailed QC sections were added in Parts 2000 through 7000. These changes are a direct and necessary result of the mandate to stay abreast of regulatory requirements and a policy intended to clarify the QC steps considered to be an integral part of each test method. Additional QC steps were added to almost half of the sections."–Pref. p. iv.
**Glucocorticoids—Advances in Research and Application: 2012 Edition**

This volume presents the proceedings of the Fifth International Conference on the Development of Biomedical Engineering in Vietnam which was held from June 16-18, 2014 in Ho Chi Minh City. The volume reflects the progress of Biomedical Engineering and discusses problems and solutions. It aims identifying new challenges, and shaping future directions for research in biomedical engineering fields including medical instrumentation, bioinformatics, biomechanics, medical imaging, drug delivery therapy, regenerative medicine and entrepreneurship in medical devices.

**Handbook of Dissolution Testing**

Provides a comprehensive review of all types of medical therapeutic delivery solutions from traditional pharmaceutical therapy development to innovative medical device therapy treatment to the recent advances in cellular and stem cell therapy development. It provides information to potentially allow future development of treatments with greater therapeutic potential and creativity. It includes associated regulatory requirements for the development of these therapies. It provides a comprehensive developmental overview on therapeutic delivery solutions. It provides overview information for both the general reader as well as more detailed references for professionals and specialists in the field.

**Aulton's Pharmaceutics**

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 edited 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 biophysically 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.

**Dissolution Theory, Methodology, and Testing**

**Analytical Techniques in the Pharmaceutical Sciences**

Authored by leading experts from academia, users and manufacturers, this book provides an authoritative account of the science and technology involved in multiparticulate drug delivery systems which offer superior clinical and technical advantages over many other specialized approaches in drug delivery. The book will cover market trends, potential benefits and formulation challenges for various types of multiparticulate systems. Drug solubility, dose, chemistry and therapeutic indications as well as excipient suitability coupled with manufacturing methods will be fully covered. Key approaches for taste-masking, delayed release and extended release of multiparticulates systems are of significant interest, especially their in-vivo and in-vitro performance. In addition, the principles of scale-up, QbD, and regulatory aspects of common materials used in this technology will be explained, as well as recent advances in materials and equipment enabling robust, flexible and cost-effective manufacture. Case studies illustrating best practices will also make the book a valuable resource to pharmaceutical scientists in industry and academia.