Dissolution Testing Apparatus

Technical Report SeriesBioavailability Methodology and RegulationIssues in Biochemistry and Biomaterials: 2011 EditionDosage Form Design ConsiderationsDrug Product Design and PerformanceApplied Biopharmaceutics & Pharmacokinetics, Sixth EditionUSP, NF.Hard CapsulesApplied Physical PharmacyOral Drug AbsorptionBiopharmaceutics Applications in Drug DevelopmentDrug Delivery SystemsOral Drug AbsorptionAnalytical Method Validation and Instrument Performance VerificationProceedings of the first International Conference on HarmonisationModern PharmaceuticsDissolution, Bioavailability & BioequivalenceSprowls' American PharmacyPharmaceutical Process Scale-UpOral Controlled Release Formulation Design and Drug DeliveryPrinciples and Perspectives in Drug Bioavailabilitysouvenir sustainable development of coastal placer mineralsPoorly Soluble DrugsBentley's Textbook of Pharmaceutics - E-BookApplied Biopharmaceutics & Pharmacokinetics, Seventh EditionDispensing of MedicationPulmonary Drug DeliveryGlucocorticoids—Advances in Research and Application: 2012 EditionHandbook of Bioequivalence TestingLaboratory PracticeAutomation of Pharmaceutical OperationsTheory and Practice of Physical Pharmacy - E-BookHandbook of Dissolution TestingLong Acting Injections and ImplantsDeveloping Solid Oral Dosage FormsIn Vitro-In Vivo CorrelationsHandbook of Pharmaceutical Analysis by HPLCNonclinical Statistics for Pharmaceutical and Biotechnology IndustriesGeneric Drug Product DevelopmentIn Vitro Drug Release Testing of Special Dosage Forms

Technical Report Series

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

Bioavailability Methodology and Regulation

Issues in Biochemistry and Biomaterials: 2011 Edition

Dosage Form Design Considerations

"Completely revised and expanded throughout. Presents a comprehensive integrated, sequenced approach to drug dosage

formulation, design, and evaluation. Indentifies the pharmacodynamic and physicochemical factors influencing drug action through various routes of administration."

Drug Product Design and Performance

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

Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition

USP, NF.

This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues.

Hard Capsules

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.

Applied Physical Pharmacy

Designed as the core textbook for the required physical pharmacy or pharmaceutics course within the pharmacy school curriculum. With a focus on examples from pharmacy practice, this book presents the chemical and physical chemical principles fundamental to the development of medication dosage forms. Numerous case studies present relevant examples of physical chemical principles in current pharmacy practice.

Oral Drug Absorption

Incl. regaining

Biopharmaceutics Applications in Drug Development

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.

Drug Delivery Systems

Oral Drug Absorption

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 biopharmaceutic 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.

Analytical Method Validation and Instrument Performance Verification

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, prefomulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

Proceedings of the first International Conference on Harmonisation

Modern Pharmaceutics

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

Dissolution, Bioavailability & Bioequivalence

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.

Sprowls' American Pharmacy

Drug therapy via inhalation route is at the cutting edge of modern drug delivery research. There has been significant progress on the understanding of drug therapy via inhalation products. However, there are still problems associated with their formulation design, including the interaction between the active pharmaceutical ingredient(s) (APIs), excipients and devices. This book seeks to cover some of the most pertinent issues and challenges of such formulation design associated with industrial production and desirable clinical outcome. The chapter topics have been selected with a view to integrating the factors that require consideration in the selection and design of device and formulation components which impact upon patient usability and clinical effectiveness. The challenges involved with the delivery of macromolecules by inhalation to both adult and pediatric patients are also covered. Written by leading international experts from both academia and industry, the book will help readers (formulation design scientists, researchers and post-graduate and specialized undergraduate students) develop a deep understanding of key aspects of inhalation formulations as well as detail ongoing challenges and advances associated with their development.

Pharmaceutical Process Scale-Up

Explores computer applications in the pharmaceutical research laboratory & production plant.

Oral Controlled Release Formulation Design and Drug Delivery

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral

Principles and Perspectives in Drug Bioavailability

souvenir sustainable development of coastal placer minerals

Poorly Soluble Drugs

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

Bentley's Textbook of Pharmaceutics - E-Book

Applied Biopharmaceutics & Pharmacokinetics, Seventh Edition

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Dispensing of Medication

Pulmonary Drug Delivery

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.

Glucocorticoids—Advances in Research and Application: 2012 Edition

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.

Handbook of Bioequivalence Testing

Drug delivery technologies represent a vast and vital area of Research and Development. The demand for innovative drug delivery systems continues to grow, and this growth continues to drive new developments. Building on the foundation provided by the first edition, Drug Delivery Systems, Second Edition covers the latest developments in both

Laboratory Practice

This book serves as a reference text for regulatory, industry and academic statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxiology sciences, and the Chemistry, Manufacturing and Controls sciences. Drug discovery and development is a long and costly process. Most decisions in the drug development process are made with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory guidance, current statistical practice, and further research directions.

Automation of Pharmaceutical Operations

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.

Theory and Practice of Physical Pharmacy - E-Book

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.

Handbook of Dissolution Testing

This history documents the gelatin capsule from its inception in the early 19th century, through to the 1990s. It gives an account of all aspects of the manufacture and filling of hard capsules.

Long Acting Injections and Implants

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

Developing Solid Oral Dosage Forms

In Vitro-In Vivo Correlations

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.

Handbook of Pharmaceutical Analysis by HPLC

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/.

Nonclinical Statistics for Pharmaceutical and Biotechnology Industries

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/.

Generic Drug Product Development

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.

In Vitro Drug Release Testing of Special Dosage Forms

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