Calibration Of Dissolution Test Apparatus | f0cc061fcafd85dca5aa2ab892a76aca

Gluco corticoids—Advances in Research and Application: 2012 Edition

Nanofibres in Drug Delivery

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 generics, 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 field. The book includes scientific contributions from over 40 scientists from over 20 countries, including leading pharmaceutical companies, government laboratories, and universities. The book is intended for drug product development and formulation scientists, quality control and assurance professionals, and regulators.

Pharmaceutical Dissolution Testing

Handbook of Preformulation

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence

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 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 Notingham 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 Raof, 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 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.

Controlled Release Veterinary Drug Delivery

This book gives information and guidance on important subjects. It presents the major and efficient applications for efficient insulin materials. The book is divided into two parts. Part I discusses ecological insulin materials. In this part, the three sub-subjects are drafting seismic aspects of the application of thermal insulation boards beneath the building’s foundations, flammability of bio-based rigid polyurethane foam thermal insulation, and the review of some commonly used methods and techniques to measure the thermal conductivity of insulation materials.

Aulton’s Pharmaceutics

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
Where To Download Calibration Of Dissolution Test Apparatus

Applied Biopharmaceutics & Pharmacokinetics, Seventh Edition

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 strategies 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.

The International Pharmacopoeia

The third edition of this introductory text covers the factors which influence the release of the drug from the drug product and how the body handles the drug. A stronger focus has been placed on the basics with clear explanations and illustrated examples. There is also more information on statistics and population pharmacokinetics and new chapters on drug distribution, computer applications, enzyme kinetics and pharmacokinetics models.

Handbook of Pharmaceutical Analysis by HPLC

Encapsulation of Active Molecules and Their Delivery System covers the key methods of preparation of encapsulation, as well as release mechanisms and their applications in food, biotechnology, metal protection, drug delivery, and micronutrients delivery in agriculture. The book also provides real-life examples of applications in food and other industries. Sections encompasses (i) Synthesis and characterization methods of micro- and nanocarriers as the delivery systems, (ii) Up-to-date encapsulation techniques in the areas of pharmaceuticals, nutraceuticals and corrosion, (iii) The release methods of the encapsulated materials, and (iv) Industry perspectives, including scale up of the processes. Focuses on encapsulation processes in chemical and materials engineering and biotechnology Provides a relevant resource for the pharmaceutical and food industries Presents wide coverage on the entrapment of molecules that scales-up to industrial sized needs

Therapeutic Delivery Solutions

Poorly Soluble Drugs

In Vitro-In Vivo Correlations

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/.

Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition

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-a-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-orals. 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.

In Vitro Drug Release Testing of Special 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 regulatory bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmacists, QA officers, and public authorities.

Analytical Method Validation and Instrument Performance Verification

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,
The Pharmacist

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 applications, 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 of 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.

The HPLC Expert


Formulation and Analytical Development for Low-Dose Oral Drug Products

In recent years there has been an explosion of interest in the production of nanoscale fibres for drug delivery and tissue engineering. Nanofibres in Drug Delivery aims to outline to new researchers in the field the utility of nanofibres in drug delivery, and to explain to them how to prepare fibres in the laboratory. The book begins with a brief discussion of the main concepts in pharmaceutical science. The authors then introduce the key techniques that can be used for fibre production and explain briefly the theory behind them. They discuss the experimental implementation of fibre production, starting with the simplest possible set-up and then moving on to consider more complex arrangements. As they do so, they draw on their own experiences in fibre production, and use examples from current literature to show how each particular type of fibre can be applied to drug delivery. They also consider how fibre production could be moved beyond the research laboratory into industry, discussing regulatory and scale-up aspects.

Handbook

A new edition of one of Zola's lesser-known novels from the Rougon-Macquart Cycle Finding the young Angélique on their doorstep one Christmas Eve, the pious Hubert couple decide to bring her up as their own. As the girl grows up in the vicinity of the town's towering cathedral and learns her parents' trade of embroidery, she becomes increasingly fascinated by the lives of the saints, a passion fueled by her reading of the Golden Legend and other mystical Christian writings. One day, when she is in the shape of Felicien Hautecoeur, enters the dream world she has constructed around herself, bringing about upheaval and distress. Although it provides a detailed portrait of provincial 19th-century life and it adheres to a naturalist approach, The Dream eschews many of the characteristics of Zola's other novels of the Rougon-Macquart cycle—such as a pronounced polemical agenda or a gritty subject matter—offering instead a timeless, lyrical tale of love and innocence.

European Pharmacopoeia

Developing Solid Oral Dosage Forms

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 biopharmaceutics studies involving drug product equivalency and unequivalency Design and evaluate dosage regimens of drugs, using pharmacokinetic and biopharmaceutical 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 Summary, 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 Japanese Pharmacopoeia

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 global regulatory authorities for CGMP 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.

Pharmaceutical Dosage Forms - Tablets

Handbook of Dissolution Testing

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

5th International Conference on Biomedical Engineering in Vietnam

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 unequivancy. 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 biopharmaceutical 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.

Handbook of Bioequivalence Testing

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.

Encyclopedia of Pharmaceutical Technology

Insulation Materials in Context of Sustainability

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

Oral Drug Absorption

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 Pharmaceutical Manufacturing Formulations, Third Edition

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