Different Types Of Dissolution Apparatus

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Drug Delivery Systems John Wiley & Sons

"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."

Pharmaceutical Dissolution Testing John Wiley & Sons

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.

Compounded Topical Pain Creams John Wiley & Sons

Coulson and Richardson's Chemical Engineering has been fully revised and updated to provide practitioners with an overview of chemical engineering. Each reference book provides clear explanations of theory and thorough coverage of practical applications, supported by case studies. A worldwide team of editors and contributors have pooled their experience in adding new content and revising the old. The authoritative

style of the original volumes 1 to 3 has been retained, but the content has been brought up to date and altered to be more useful to practicing engineers. This complete reference to chemical engineering will support you throughout your career, as it covers every key chemical engineering topic. Coulson and Richardson ' s Chemical Engineering: Volume 1B: Heat and Mass Transfer: Fundamentals and Applications, Seventh Edition, covers two of the main transport processes of interest to chemical engineers: heat transfer and mass transfer, and the relationships among them. Covers two of the three main transport processes of interest to chemical engineers: heat transfer and mass transfer, and the relationships between them Includes reference material converted from textbooks Explores topics, from foundational through technical Includes emerging applications, numerical methods, and computational tools

Generic Drug Product Development

Cuvillier Verlag

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

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

FDA By-lines CRC Press

Organic Materials as Smart Nanocarriers for Drug Delivery presents the latest developments in the area of organic frameworks used in pharmaceutical

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

Pharmaceutical Amorphous Solid Dispersions

William Andrew

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

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

Effects of Operating and Geometric Variables on Hydrodynamics and Tablet Dissolution in Standard and Modified Dissolution Testing Apparatuses 2Dissolution testing is routinely conducted in the pharmaceutical industry to provide critical in vitro drug release information for quality control purposes, and especially to assess batch-to-batch consistency of solid oral dosage forms such as tablets. Among the different types of apparatuses listed in the United States Pharmacopoeia (USP), the most commonly used dissolution system for

solid dosage forms is the USP Dissolution Testing Apparatus 2, consisting of an unbaffled, hemispherical-bottomed vessel equipped with a 2-blade radial impeller. Despite its extensive use in industry and a large body of work, some key aspects of the hydrodynamics of Apparatus 2 have received very little attention, such as the determination of its power dissipation requirements (which controls solid-liquid mass transfer processes) and the velocity distribution under the different agitation conditions at which this system is routinely operated. In addition, the tablet dissolution performance of Apparatus 2 has been shown to be highly sensitive to a number of small geometric factors, such as the exact locations of the impeller and the dissolving tablet. Therefore, in this study, computation and experimental work was conducted to (a) quantify the roles of some key hydrodynamic variables of importance for the standard Apparatus 2 system and determine their impact on the dissolution profiles of solid dosage forms, and (b) design and test a modified Apparatus 2 that can overcome the major limitations of the standard system, and especially those related to the sensitivity of the current apparatus to tablet location. Accordingly, the hydrodynamics in the standard USP Apparatus 2 vessel was experimentally quantified using Laser-Doppler Velocimetry (LDV) and Particle Image Velocimetry (PIV). Complete experimental mapping of the velocity distribution inside the standard Apparatus 2 was obtained at three agitation intensities, i.e., 50 rpm (NRe=4939), 75 rpm (NRe= 7409) and 100 rpm (NRe= 9878). The velocity distributions from both LDV and PIV were typically found to be very similar. It was found that the overall flow

pattern throughout the whole vessel was dominated by the tangential component of the velocity at all agitation speeds, whereas the magnitudes of the axial and radial velocity components were typically much smaller. In the bottom zone of the vessel, two regions were observed, i.e., a central, low-velocity inner core region, and an outer recirculation loop below the impeller, rotating around the central inner core region. This core region typically persisted, irrespective of the impeller agitation speed. Computation Fluid Dynamics (CFD) was additionally used to predict velocity profiles. Typically, the CFD predictions matched well the experimental results. The power dissipated by the impeller in Apparatus 2 was experimentally measured using a frictionless system coupled with torque measurement. CFD was additionally used to predict the power consumption, using two different approaches, one based on the integration of the local value of the energy dissipation rate, and the other based on the prediction of the pressure distribution on the impeller blade, from which the torque and the power required to rotate the impeller were predicted. The agreement between the experimental data and both types of numerical predictions was found to be quite satisfactory in most cases. The results were expressed in terms of the non- dimensional Power number, Po, which was typically found to be on the order of ~0.3. The power number was observed to decrease very gradually with increasing agitation speeds. The results of this work and of previous work with the standard USP Apparatus 2 confirm that this apparatus is very sensitive to the location of the tablet, which is typically not controlled in a typical test since

the tablet is dropped into the vessel at the beginning of the test and it may rest at random locations on the vessel bottom. Therefore, in this work a modified USP Dissolution Testing Apparatus 2, in which the impeller was placed 8-mm off-center in the vessel, was designed and tested. This design eliminates the poorly mixed inner core region below the impeller observed in the standard Apparatus 2 vessel. Dissolution tests were conducted with the Modified Apparatus for different tablet locations using both disintegrating calibrator tablets (Prednisone) and non-disintegrating calibrator tablets (Salicylic Acid). The experimental data clearly showed that all dissolution profiles in the Modified Apparatus were not affected by the tablet location at the bottom of the vessel. This design can effectively eliminate artifacts generated by having the tablet settle randomly at different locations on the vessel bottom after dropping it at the beginning of a dissolution testing experiment. The hydrodynamic and mixing characteristics of the modified Apparatus 2 were studied in some detail by experimentally measuring and computationally predicting the velocity distribution, power dissipation, and mixing time in the modified system. The velocity profiles near the bottom of the vessel were found to be significantly more uniform than in the standard Apparatus 2, because of the elimination of the poorly mixed zone below the impeller. The power dissipation in the modified Apparatus 2 was typically higher than in the standard system, as expected for an non-symmetrical system, and the corresponding Power number, Po, was less dependent on Reynolds number than Po in the standard system. Finally, the mixing time in the

modified system, as experimentally measured by using a decolorization method and computationally predicted through CFD simulation, was found to be shorter in the modified Apparatus 2 by 7.7 %-12.9 % as compared to Apparatus 2. It can be concluded that the modified Apparatus 2 is a more robust testing apparatus, which is capable of producing dissolution profiles that are less sensitive to small geometric factors that play a major role in the standard USP Apparatus 2.Oral Drug Absorption

Providing a roadmap from early to late stages of drug development,this book overviews amorphous solid dispersion technology – aleading platform to deliver poorly water soluble drugs, a majorhurdle in today ' s pharmaceutical industry. · Helps readers understand amorphous solid dispersionsand apply techniques to particular pharmaceutical systems · Covers physical and chemical properties, screening,scale-up, formulation, drug product manufacture, intellectualproperty, and regulatory considerations · Has an appendix with structure and propertyinformation for polymers commonly used in drug development and withmarketed drugs developed using the amorphous sold dispersionapproach · Addresses global regulatory issues including USAregulations, ICH guidelines, and patent concerns around theworld

Aulton's Pharmaceutics CRC Press

This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters,

the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol ® , and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

Pharmaceutical Press

Written to help companies comply with GMP, GLP, and validation requirements imposed by the FDA and regulatory bodies worldwide, Quality Control Training Manual: Comprehensive Training Guide

for API, Finished Pharmaceutical and Biotechnologies Laboratories presents cost-effective training courses that cover how to apply advances in the life sciences

In Vitro-In Vivo Correlations John Wiley & Sons

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

Innovative Dosage Forms Elsevier Health Sciences

Principles of Biomedical Sciences and Industry Improve your product development skills to bring new ideas to biomedicine The development of innovative healthcare products, such as biodegradable implants, biopharmaceuticals, or companion diagnostics, requires a multi-disciplinary approach that incorporates scientific evidence with novel and innovative ideas to create new and improved products and treatments. Indeed, product development and the integration of science with commercial aspects have become key challenges for scientists working in the pharmaceutical, biotech, and medtech industries. Using a multi-pronged approach to development, Principles of Biomedical Sciences and Industry combines ideas and

methodologies from four of the central areas of focus in the biomedical arena: pharmaceuticals, diagnostics, biomaterials, and medical devices. In doing so, the book covers the entire product lifecycle, from translating a scientific idea into a prototype to product development, launch, and management. Principles of Biomedical Sciences and Industry readers will also find: Several case studies from the most important product categories (pharmaceuticals, diagnostics, medical devices, combination products) Chapters dealing with toxicology and safety risks in development, as well as regulatory approval Key business aspects including how to secure funding, managing intellectual property, and price regulation in the market An ideal resource for teachers and students that conveys the information in an easily-digestible format Ideal for advanced students and young professionals pursuing a career in the biomedical and healthcare industries, Principles of Biomedical Sciences and Industry is an essential reference for those in pharmaceutical industry, biotechnologists, medicinal chemists, bio-engineers, pharma engineers, and management consultants.

Water-Insoluble Drug Formulation John Wiley & Sons

Remington: The Science and Practice of Pharmacy, Twenty Third Edition, offers a trusted, completely updated source of information for education, training, and development of pharmacists. Published for the first time with Elsevier, this edition

includes coverage of biologics and biosimilars as uses of those therapeutics have increased substantially since the previous edition. Also discussed are formulations, drug delivery (including prodrugs, salts, polymorphism. With clear, detailed color illustrations, fundamental information on a range of pharmaceutical science areas, and information on new developments in industry, pharmaceutical industry scientists, especially those involved in drug discovery and development will find this edition of Remington an essential reference. Intellectual property professionals will also find this reference helpful to cite in patents and resulting litigations. Additional graduate and postgraduate students in Pharmacy and Pharmaceutical Sciences will refer to this book in courses dealing with medicinal chemistry and pharmaceutics. Contains a comprehensive source of principles of drug discovery and development topics, especially for scientists that are new in the pharmaceutical industry such as those with trainings/degrees in chemistry and engineering Provides a detailed source for formulation scientists and compounding pharmacists, from produg to excipient issues Updates this excellent source with the latest information to verify facts and refresh on basics for professionals in the broadly defined pharmaceutical industry

Forecasting the in Vivo Performance of Modified Release (MR) Dosage Forms Using Biorelevant Dissolution Tests CRC Press Teaches future and current drug developers the

latest innovations in drug formulation design and optimization This highly accessible, practice-oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies, including the use of functional excipients to enhance solubility and stability. It covers oral, intravenous, topical, and parenteral administration routes. The book also discusses safety aspects of drugs and excipients, as well as regulatory issues relevant to formulation. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development. It then offers readers reliable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. -Provides information that is essential for the drug development effort -Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and cocrystals -Describes current approaches in early pre-formulation to achieve the best in vivo results -Addresses regulatory and safety aspects, which are key considerations for pharmaceutical

companies -Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative Dosage Forms: Design and Development at Early Stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists, pharmaceutical chemists, and pharmacologists.

Physical Pharmacy Springer Science & Business Media

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.

In Vitro Drug Release Testing of Special Dosage Forms John Wiley & Sons

FASTtrack Pharmaceutics – Dosage Form and Design focuses on what you really need to know in order to pass your pharmacy exams. It provides concise, bulleted information, key points, tips and an all-important self-assessment section, including MCQs.

Handbook of Chemical Engineering

Pharma Career Publications

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

Dosage Form Design Considerations CRC Press

Effects of Operating and Geometric Variables on Hydrodynamics and Tablet Dissolution in Standard and Modified Dissolution Testing Apparatuses 2

Coulson and Richardson's Chemical Engineering CRC Press

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.

Biopharmaceutics of Fatty Suspension Suppositories Springer

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

Academic Press

Introduction, Historical Highlights, and the Need for Dissolution Testing Theories of Dissolution Dissolution Testing Devices Automation in Dissolution Testing, by William A. Hanson and Albertha M. Paul Factors That Influence Dissolution Testing Interpretation of Dissolution Rate Data Techniques and of In Vivo Dissolution, by Umesh V. Banakar, Chetan D. Lathia, and John H. Wood Dissolution of Dosage Forms Dissolution of Modified-Release Dosage Forms Dissolution and Bioavailability Dissolution Testing and the Assessment of Bioavailability/Bioequivalence, by Santosh J. Vetticaden Dissolution Rediscovered, by John H. Wood Appendix: USP/NF Dissolution Test.