
Dissolution Apparatus Principle

Principles, Practice and Economics of Plant and Process Design
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Plenary Lectures Presented at the Fourth Polish Conference on Analytical Chemistry
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Proceedings of the AAPS Dietary Supplements Forum
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Solid Oral Dosage Forms, Second Edition
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Principles, Practice and Economics of Plant and Process Design
Springer Science & Business Media

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.

Drug Delivery Systems CRC Press

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/Toxicology 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.

The Law of Nations Academic Press

Part I: Process design -- Introduction to design -- Process flowsheet development -- Utilities and energy efficient design -- Process simulation -- Instrumentation and process control -- Materials of construction -- Capital cost estimating -- Estimating

revenues and production costs -- Economic evaluation of projects -- Safety and loss prevention -- General site considerations -- Optimization in design -- Part II: Plant design -- Equipment selection, specification and design -- Design of pressure vessels -- Design of reactors and mixers -- Separation of fluids -- Separation columns (distillation, absorption and extraction) -- Specification and design of solids-handling equipment -- Heat transfer equipment -- Transport and storage of fluids.

Chemical Vapor Transport Reactions Academic Press

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.

The Science of Dosage Form Design Marcel Dekker

Incorporated

A comprehensive textbook covering the design of dosage forms and all aspects of drug delivery systems. 'Pharmaceutics' in its broadest sense is the 'art of the apothecary' or, in simple terms, pharmaceutical preparations. It remains a diverse subject in the pharmacy curriculum, encompassing design of drugs, their manufacture, and the elimination of micro-organisms from the products. This book encompasses all those areas and pays particular attention to the design of dosage forms and their manufacture.

Aulton's Pharmaceutics CRC Press

"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.

for Pharmacy 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 Dissolution Testing Elsevier

This comprehensive up-to-date guide and information source is an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms. The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products.

Principles in Drug Development Springer Science & Business Media

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 pharmaceuticals 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 pharmaceuticals 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.

Pharmaceutical Dosage Forms Elsevier

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an

almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of

the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Applications of Pharmacokinetic Principles in Drug Development
World Health Organization

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.

Plenary Lectures Presented at the Fourth Polish Conference on Analytical Chemistry UCL Press

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 Formulation, Processing and Manufacturing Springer Science & Business Media

Over half of the adult population in the U.S. includes some sort of dietary supplement in their diet. This book provides the reader with a better understanding of the science and quality issues of dietary supplements. It explains terms regarding supplements, regulatory implications and standards of botanical extracts, and provides background on the supplement industry and pharmacoeconomics of supplements. It also identifies the health benefits and risks.

Biopharmaceutics Applications in Drug Development
Academic Press

This 6th edition of the established textbook covers every aspect of drug properties from the design of dosage forms to their delivery by all routes to sites of action in the body.

Physicochemical Principles of Pharmacy Walter de Gruyter
Drug Delivery Systems examines the current state of the field within pharmaceutical science and concisely explains the history of drug delivery systems, including key developments. The book translates the physicochemical properties of drugs into drug delivery systems administered via various routes, such as oral,

parenteral, transdermal and inhalational. Regulatory and product development topics are also explored. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of drug delivery systems within the pharmaceutical sciences industry and research, as well as in chemical engineering. Each chapter delves into a particular aspect of this fundamental field to cover the principles, methodologies and technologies employed by pharmaceutical scientists. This book provides a comprehensive examination that is suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnologies, and related industries. Provides up-to-date information on how to translate the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various routes, such as oral, parenteral, transdermal and inhalational Contains extensive references and further reading for course and self-study

In Vitro Drug Release Testing of Special Dosage Forms CRC Press
Pharmaceutics: Basic Principles and Application to Pharmacy Practice is an engaging textbook that covers all aspects of pharmaceutics with emphasis on the basic science and its application to pharmacy practice. Based on curricular guidelines mandated by the American Council for Pharmacy Education (ACPE), this book incorporates laboratory skills by identifying portions of each principle that can be used in a clinical setting. In this way, instructors are able to demonstrate their adherence to ACPE standards and objectives, simply by using this book. Written in a straightforward and student-friendly manner, Pharmaceutics enables students to gain the scientific foundation

to understand drug physicochemical properties, practical aspects of dosage forms and drug delivery systems, and the biological applications of drug administration. Key ideas are illustrated and reinforced through chapter objectives and chapter summaries. A companion website features resources for students and instructors, including videos illustrating difficult processes and procedures as well as practice questions and answers. Instructor resources include Powerpoint slides and a full-color image bank. This book is intended for students in pharmaceutical science programs taking pharmaceutics or biopharmaceutics courses at the undergraduate, graduate and doctoral level. Chapter objectives and chapter summaries illustrate and reinforce key ideas Designed to meet curricular guidelines for pharmaceutics and laboratory skills mandated by the Accreditation Council for Pharmacy Education (ACPE) Companion website features resources for students and instructors, including videos illustrating difficult processes and procedures and practice questions and answers. Instructor resources include Powerpoint slides and a full-color image bank

Proceedings of the AAPS Dietary Supplements Forum
Pharmaceutical Dissolution Testing

There has not, until now, been a single up-to-date volume to provide those in drug R&D with practical information on all aspects of solid dispersion technology for drugs. This forthcoming volume finally provides such a guide and reference. The unified presentation by a team of specialists in this field is designed for practical application. Theoretical concepts are covered for a fuller understanding of current techniques. All significant recent developments are included.

Principles and Applications of Biopharmaceutics and Pharmacokinetics 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

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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

Basic Principles and Application to Pharmacy Practice CRC Press
Pharmaceutical Dissolution TestingCRC Press

Pharmaceutics Pharma Career Publications

In this concise and systematic book, a team of experts select the most important, cutting-edge technologies used in drug delivery systems. They take into account significant drugs, new technologies such as nanoparticles, and therapeutic applications. The chapters present step-by-step laboratory protocols following the highly successful Methods in Molecular Biology™ series format, offering readily reproducible results vital for pharmaceutical physicians and scientists.