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Innovative Dosage Forms John Wiley & Sons
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.

In Vitro-In Vivo Correlations CRC Press
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.

Strategies to Modify the Drug Release from Pharmaceutical Systems John Wiley & Sons

First Published in 1987, this book offers a full, comprehensive guide to the process of administering the correct dosage in medicine. Carefully compiled and filled with a vast repertoire of notes, diagrams, and references this book serves as a useful reference for students of medicine, and other practitioners in their respective fields.

Handbook of Pharmaceutical Salts Properties, Selection, and Use CRC 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.

3D Printed Microfluidic Devices Springer Science & Business Media

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.

Indian Pharmacopoeia, 2007

John Wiley & Sons

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

Developing Solid Oral Dosage Forms 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.

Nitroglycerin Sustained Release Tablet. Formulation Design and Evaluation CRC Press

The COSMO-RS technique is a novel method for predicting the thermodynamic properties of pure and mixed fluids which are important in many areas, ranging from chemical engineering to drug design. COSMO-RS, From Quantum Chemistry to Fluid Phase Thermodynamics and Drug Design is

about this novel technology, which has recently proven to be the most reliable and efficient tool for the prediction of vapour-liquid equilibria. In contrast to group contribution methods, which depend on an extremely large number of experimental data, COSMO-RS calculates the thermodynamic data from molecular surface polarity distributions, resulting from quantum chemical calculations of the individual compounds in the mixture. In this book, the author cleverly combines a vivid overview of the partly demanding theoretical steps with a deeper analysis of their scientific background and justification. Aimed at theoretical chemists, computational chemists, physical chemists, chemical engineers, thermodynamicists as well as students,academic and industrial experts, COSMO-RS, From Quantum Chemistry to Fluid Phase Thermodynamics and Drug Design provides a novel viewpoint to anyone looking to gain more insight into the theory and potential of the unique method, COSMO-RS. The only book currently available on COSMO-RS technique Provides a novel viewpoint for the scientific understanding and for the practical quantitative treatment of fluid phase thermodynamics Includes illustrative examples of the COSMOtherm program

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence MDPI

1. Evolution of dissolution

testing 5; 2. Theory of dissolution 11; 3. Theoretical concepts for the release of a drug from dosage forms 37; 4. Effect of the physicochemical properties of the drug on dissolution rate 53; 5. Factors affecting the rate of dissolution of solid dosage forms 73; 6. Effects of storage and packaging on the dissolution of drug formulations 107; 7. Factors relating to the dissolution apparatus 115; 8. Effect of the test parameters on dissolution rate 145; 9. Dissolution of suspensions 173; 10. Dissolution of topical dosage forms (creams, gels, and ointments) 189; 11. Dissolutions of suppositories 205; 12. Dissolution characteristics of controlled-release systems 215; 13. Methods for enhancement of the drug-dissolution characteristics 265; 14. Developing a new dissolution method 285; 15. Bioavailability, definitions and historical perspective 297; 17. In vitro modeling for drug absorption 315; 18. Pharmacokinetic considerations in bioavailability studies 335; 19. Bioavailability and variations in drug blood levels 367; 20. Bioavailability and the biologic response 385; 21. Measurements

of bioavailability 399; 22. General issues to be considered in conducting bioavailability studies 415; 23. Bioavailability of controlled-release dosage forms 425; 24. In vivo release and bioavailability of topical preparations 437; 25. Methods for enhancement of bioavailability 455; 26. Bioequivalence: general definitions 477; 27. Bioequivalence: case histories 481; 28. Correlation of in vitro rate of dissolution with in vivo bioavailability 491; 29. Determination of bioequivalence and its regulatory aspects 517; 30. The official bioequivalence protocols and therapeutic equivalence 533.

Aulton's Pharmaceutics John Wiley & Sons

Particularly in healthcare fields, there is growing movement away from traditional lecture style course towards active learning and team-based activities to improve learning and build higher level thinking through application of complex problems with a strong foundation of facts and data. Essential Pharmaceutics is suited to this modern teaching style, and is the first book of its kind to provide the resources and skills needed for

successful implementation of an active learning pharmaceutics course.This text offers a format that is specifically suited for integration in an active learning, team-based classroom setting. It is ideal for self-learning for the beginning pharmaceutics student, based upon the extensive utilization of figures, tables, and its overview of essential topics in pharmaceutics. Also unique to this text is the integration of case studies based upon modern pharmaceutical products which are designed to reinforce importance pharmaceutical concepts and teach essential skills in literature review and patent searching. Case studies covering all topics covered in the text have been developed by the authors that allow application of the content in the flipped-classroom pharmaceutical course.

Dosage Form Design Parameters

World Health Organization

Controlled Release in Oral Drug Delivery provides focus on specific topics, complementing other books in the initial CRS series. Each chapter sets the context for the inventions described and describe the latitude that the inventions allow. In order to provide some similar look to each chapter, the

coverage includes the historical overview, candidate drugs, factors influencing design and development, formulation and manufacturing and delivery system design. This volume was written along three main sections: the relevant anatomy and physiology, a discussion on candidates for oral drug delivery and the major three groups of controlled release systems: diffusion control (swelling and inert matrices); environmental control (pH sensitive coatings, time control, enzymatic control, pressure control) and finally lipidic systems.

Extended-Release Dosage Forms Elsevier

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

The Impact of Food Bioactives on Health Springer

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.

Analysis of Pharmaceuticals by Capillary Electrophoresis CRC Press

Explore the latest research in biopharmaceutics from leading contributors in the field In Biopharmaceutics - From Fundamentals to Industrial Practice, distinguished Scientists from the UK's Academy of Pharmaceutical Sciences Biopharmaceutica Focus Group deliver a comprehensive examination of the tools used within the field of biopharmaceutics and their applications to drug development. This edited volume is an indispensable tool for anyone seeking to better understand the field of biopharmaceutics as it rapidly develops and evolves. Beginning with an expansive introduction to the basics of biopharmaceutics and the context that underpins the field, the included resources go on to discuss how biopharmaceutics are integrated into product development within the pharmaceutical industry. Explorations of how the

regulatory aspects of biopharmaceutics function, as well as the impact of physiology and anatomy on the rate and extent of drug absorption, follow. Readers will find insightful discussions of physiologically based modeling as a valuable asset in the biopharmaceutics toolkit and how to apply the principles of the field to special populations. The book goes on to discuss: Thorough introductions to biopharmaceutics, basic pharmacokinetics, and biopharmaceutics measures Comprehensive explorations of solubility, permeability, and dissolution Practical discussions of the use of biopharmaceutics to inform candidate drug selection and optimization, as well as biopharmaceutics tools for rational formulation design In-depth examinations of biopharmaceutics classification systems and regulatory biopharmaceutics, as well as regulatory biopharmaceutics and the impact of anatomy and physiology Perfect for professionals working in the pharmaceutical and biopharmaceutical industries, Biopharmaceutics - From Fundamentals to Industrial

Practice is an incisive and up-to-date resource on the practical, pharmaceutical applications of the field.

Basic Tests for Pharmaceutical Dosage Forms Academic Press
Describes analytical methods development, optimization and validation, and provides examples of successful methods development and validation in high-performance liquid chromatography (HPLC) areas. The text presents an overview of Food and Drug Administration (FDA)/International Conference on Harmonization (ICH) regulatory guidelines, compliance with validation requirements for regulatory agencies, and methods validation criteria stipulated by the US Pharmacopia, FDA and ICH.

Ocular Transporters and Receptors Springer Nature
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.

Analytical Method Development and Validation American Bar Association

Dosage Form Design Parameters, Volume II, 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

Oral Drug Absorption Springer Science & Business Media

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.

In Vitro Drug Release Testing of Special Dosage Forms GRIN Verlag

"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."

Generic Drug Product Development Academic Press

Since the earliest dosage forms to modern drug delivery systems, came a great development and growth of knowledge with respect to drug delivery. Strategies to Modify the Drug Release from Pharmaceutical Systems will address principles, systems, applications and advances in the field.It will be principally a textbook and a reference source of strategies to modify the drug release. Moreover, the characterization, mathematical and

physicochemical models, applications and the systems will be discussed. Addresses the principles, systems, applications and advances in the field of drug delivery Highlights the mathematical and physicochemical principles related to strategies Discusses drug release and its possible modifications