Drug Stability Principles And Practices

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Drug Stability
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Conflict of Interest in Medical Research, Education, and Practice
Fundamentals of Drug Delivery
Drug Stability
Remington Education Pharmaceutics
Modern Pharmaceutics Volume 1
Solid State Development and Processing of Pharmaceutical Molecules
Drug-like Properties: Concepts, Structure Design and Methods
Pharmaceutical Quality by Design
Extended Stability for Parenteral Drugs
Drug Delivery
Development and Validation of Analytical Methods
Predictive Modeling of Pharmaceutical Unit Operations
Developing Solid Oral Dosage Forms
Statistical Design and Analysis of Stability Studies
Guideline for Submitting Samples and Analytical Data for Methods Validation
Making Medicines Affordable
Drug Stability, Third Edition, Revised, and Expanded
Drug Stability for Pharmaceutical Scientists
Innovative Dosage Forms
Pharmaceutical Manufacturing Handbook
Guideline on General Principles of Process Validation
Rare Diseases and Orphan Products
Remington
Stability of Drugs and Dosage Forms
Aulton's Pharmaceutics
Trissel's Stability of Compounded Formulations
Pharmaceutical Manufacturing Handbook
The Pharmaceutical CODEX: Principles & Practice of Pharmaceutics, 12e (HB)
How to Develop Robust Solid Oral Dosage Forms
Handbook of Stability Testing in Pharmaceutical Development
Modern Methods of Clinical Investigation
Chemical Stability of Pharmaceuticals
Accelerated Predictive Stability (APS)
Pharmaceutical Biotechnology
Pharmaceutical Stability Testing to Support Global Markets
Drug Stability and Chemical Kinetics
Disease Control Priorities, Third Edition (Volume 6)

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Practical Psychopharmacology Springer
Rare diseases collectively affect millions of Americans of all ages, but developing drugs and medical devices to prevent, diagnose, and treat these conditions is challenging. The Institute of Medicine (IOM) recommends implementing an integrated national strategy to promote rare diseases research and product development.
Drug Stability Springer Science & Business Media
Practical advice on the problems of carrying out a testing program, written with the stability scientist in mind. Presents basic theory, industrial practice, and regulatory aspects, taking the reader from stability principles of the drug in dissolved, dispersed, and solid states through data analysis of the packaged drug's stability and experimental methods for achieving stable marketed products. Features computer programs, many diagrams and tables, and some 500 references. Annotation(c) 2003 Book News, Inc., Portland, OR (booknews.com)
Analytical Techniques in the Pharmaceutical Sciences John Wiley & Sons
A practical guide translating clinical trials findings, across major psychiatric disorders, to devise tailored, evidence-based treatments.
Conflict of Interest in Medical Research, Education, and Practice Elsevier Health Sciences
Of the thousands of novel compounds that a drug discovery project team invents and that bind to the therapeutic target, typically only a fraction of these have sufficient ADME/Tox properties to become a drug product. Understanding ADME/Tox is critical for all drug researchers, owing to its increasing importance in advancing high quality candidates to clinical studies and the processes of drug discovery. If the properties are weak, the candidate will have a high risk of failure or be less desirable as a drug product. This book is a tool and resource for scientists engaged in, or preparing for, the selection and optimization process. The authors describe how properties affect in vivo pharmacological activity and impact in vitro assays. Individual drug-like properties are discussed from a practical point of view, such as solubility, permeability and metabolic stability, with regard to fundamental understanding, applications of property data in drug discovery and examples of structural modifications that have achieved improved property performance. The authors also review various methods for the screening (high throughput), diagnosis (medium throughput) and in-depth (low throughput) analysis of drug properties. - Serves as an essential working handbook aimed at scientists and students in medicinal chemistry - Provides practical, step-by-step guidance on property fundamentals, effects, structure-property relationships, and structure modification strategies - Discusses improvements in pharmacokinetics from a practical chemist's standpoint
Fundamentals of Drug Delivery CRC Press
This handbook is the first to cover all aspects of stability testing in pharmaceutical

development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Drug Stability John Wiley & Sons

Solid State Development and Processing of Pharmaceutical Molecules A guide to the lastest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain. The authors—noted experts on the topic—examine the importance of the solid state form of chemical and biological drugs and review the development, production, quality control, formulation, and stability of medicines. The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality. It also includes information on relevant regulatory and intellectual property considerations. This resource is aimed at professionals in the pharmaceutical industry and offers an in-depth examination of the commercially relevant issues facing developers, producers and distributors of drug substances. This important book: Provides a guide for the effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation, process control, and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists, pharmaceutical industry professionals, pharma engineers, solid state chemists, chemical engineers, Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production.

Remington Education Pharmaceutics John Wiley & Sons

Infectious diseases are the leading cause of death globally, particularly among children and young adults. The spread of new pathogens and the threat of antimicrobial resistance pose particular challenges in combating these diseases. Major Infectious Diseases identifies feasible, cost-effective packages of interventions and strategies across delivery platforms to prevent and treat HIV/AIDS, other sexually transmitted infections, tuberculosis, malaria, adult febrile illness, viral hepatitis, and neglected tropical diseases. The volume emphasizes the need to effectively address emerging antimicrobial resistance, strengthen health systems, and increase access to care. The attainable goals are to reduce incidence, develop innovative approaches, and optimize existing tools in resource-constrained settings.

Modern Pharmaceutics Volume 1 National Academies Press

This book comprehensively reviews drug stability and

chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical kinetics, and providing numerous examples in the form of illustrations, tables and calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry, medicinal chemistry and biopharmaceutics.

Solid State Development and Processing of Pharmaceutical Molecules National Academies Press

A comprehensive guide to the current research, major challenges, and future prospects of controlled drug delivery systems Controlled drug delivery has the potential to significantly improve therapeutic outcomes, increase clinical benefits, and enhance the safety of drugs in a wide range of diseases and health conditions. Fundamentals of Drug Delivery provides comprehensive and up-to-date coverage of the essential principles and processes of modern controlled drug delivery systems. Featuring contributions by respected researchers, clinicians, and pharmaceutical industry professionals, this edited volume reviews the latest research in the field and addresses the many issues central to the development of effective, controlled drug delivery. Divided in three parts, the book begins by introducing the concept of drug delivery and discussing both challenges and opportunities within the rapidly evolving field. The second section presents an in-depth critique of the common administration routes for controlled drug delivery, including delivery through skin, the lungs, and via ocular, nasal, and otic routes. The concluding section summarizes the current state of the field and examines specific issues in drug delivery and advanced delivery technologies, such as the use of nanotechnology in dermal drug delivery and advanced drug delivery systems for biologics. This authoritative resource: Covers each main stage of the drug development process, including selecting pharmaceutical candidates and evaluating their physicochemical characteristics Describes the role and application of mathematical modelling and the influence of drug transporters in pharmacokinetics and drug disposition Details the physiology and barriers to drug delivery for each administration route Presents a historical perspective and a look into the possible future of advanced drug delivery systems Explores nanotechnology and cell-mediated drug delivery, including applications for targeted delivery and toxicological and safety issues Includes comprehensive references and links to the primary literature Edited by a team of of internationally-recognized experts, Fundamentals of Drug Delivery is essential

reading for researchers, industrial scientists, and advanced students in all areas of drug delivery including pharmaceutics, pharmaceutical sciences, biomedical engineering, polymer and materials science, and chemical and biochemical engineering.
Drug-like Properties: Concepts, Structure Design and Methods Academic Press
With over 100 illustrations, Volume 1 addresses the core disciplines of pharmaceutics (absorption, PK, excipients, tablet dosage forms, and packaging), and explores the challenges and paradigms of pharmaceutics.Key topics in Volume 1 include: principles of drug absorption, chemical kinetics, and drug stability pharmacokinetics the effect of rout
Pharmaceutical Quality by Design Academic 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.
Extended Stability for Parenteral Drugs Springer Nature
Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed untreatable. At the same time, however, the United

States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that have occurred in recent years, finding a way to make prescription medicinesâ€"and health care at largeâ€"more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all of these factors together. The current high and increasing costs of prescription drugsâ€"coupled with the broader trends in overall health care costsâ€"is unsustainable to society as a whole. Making Medicines Affordable examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This report explores structural and policy factors influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care.

Drug Delivery Academic Press

The US Food and Drug Administration's Report to the Nation in 2004 and 2005 indicated that one of the top reasons for drug recall was that stability data did not support existing expiration dates. Pharmaceutical companies conduct stability studies to characterize the degradation of drug products and to estimate drug shelf life. Illustrating how sta

Development and Validation of Analytical Methods Springer Science & Business Media

Addressing concerns for patient welfare while protecting producer reputation, and providing a database for formulation of other products, this multiauthored reference blends fundamental theory and practical advice on drug product stability in scientific, technical, and regulatory environments, covering development of indicating assays, computer use, clinical trial materials, strategic planning, and packaging. Describing the documentation required to minimize the changes of regulatory citations, the book lists manufacturers of photostability testing chambers, stability system software, and laboratory information management systems for pharmaceutical applications.

Predictive Modeling of Pharmaceutical Unit

Operations National Academies Press Collaborations of physicians and researchers with industry can provide valuable benefits to society, particularly in the translation of basic scientific discoveries to new therapies and products. Recent reports and news stories have, however, documented disturbing examples of relationships and practices that put at risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine. Conflict of Interest in Medical Research, Education, and Practice provides a comprehensive look at conflict of interest in medicine. It offers principles to inform the design of policies to identify, limit, and manage conflicts of interest without damaging constructive collaboration with industry. It calls for both short-term actions and long-term commitments by institutions and individuals, including leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, and drug, device, and pharmaceutical companies. Failure of the medical community to take convincing action on conflicts of interest invites additional legislative or regulatory measures that may be overly broad or unduly burdensome. Conflict of Interest in Medical Research, Education, and Practice makes several recommendations for strengthening conflict of interest policies and curbing relationships that create risks with little benefit. The book will serve as an invaluable resource for individuals and organizations committed to high ethical standards in all realms of medicine.

Developing Solid Oral Dosage Forms Pharmaceutical Press

The very rapid pace of advances in biomedical research promises us a wide range of new drugs, medical devices, and clinical procedures. The extent to which these discoveries will benefit the public, however, depends in large part on the methods we choose for developing and testing them. Modern Methods of Clinical Investigation focuses on strategies for clinical evaluation and their role in uncovering the actual benefits and risks of medical innovation. Essays explore differences in our current systems for evaluating drugs, medical devices, and clinical procedures; health insurance databases as a tool for assessing treatment outcomes; the role of the medical profession, the Food and Drug Administration, and industry in stimulating the use of evaluative methods; and more. This book will be of special interest to policymakers, regulators, executives in the medical industry, clinical researchers, and physicians.

Statistical Design and Analysis of Stability Studies Woodhead Publishing

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more

than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Guideline for Submitting Samples and Analytical Data for Methods Validation National Academies Press

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. - Explains the commonly used modeling and simulation tools - Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing - Practical examples of the application of modeling tools through case studies - Discussion of modeling techniques used for a risk-based approach to regulatory filings - Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

Making Medicines Affordable John Wiley & Sons

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

Drug Stability, Third Edition, Revised, and Expanded American Pharmacists Association (APhA)

"Helps readers determine whether formulated compounds will be stable for the anticipated duration of use; properly store and repackage compounded formulations; formulate in accordance with documented standards; and, counsel patients on the use and storate of comounded medications." -- Back cover.