Polymorphism In The Pharmaceutical Industry

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Pharmaceutical Salts and Co-crystals John Wiley & Sons
Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discussesvarious issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials, mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time
Polymorphism in Molecular Crystals Ssci
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.
The Textbook of Pharmaceutical Medicine Humana Press
Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology. Find out more about the series here.
Modern Pharmaceutical Industry Jones & Bartlett Publishers
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.
Polymorphism in the Pharmaceutical Industry Oxford University Press
This handbook is a definitive, up-to-date, and succinct text covering the legislative requirements, scientific foundations, and clinical good practice necessary for clinical, academic, and healthcare research.
Innovative Dosage Forms Royal Society of Chemistry
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
Dosage Form Design Parameters John Wiley & Sons
Edited by one of the leading experts in the field, this handbook emphasizes why solid-state issues are important, which approaches should be taken to avoid problems and exploit the opportunities offered by solid state properties in the pharmaceutical and agricultural industries. With its practical approach, this is at once a guideline for development chemists just entering the field as well as a high-quality source of reference material for specialists in the pharmaceutical and chemical industry, structural chemists, physicochemists, crystallographers, inorganic chemists, and patent departments.
Six Sigma in the Pharmaceutical Industry John Wiley & Sons
Research in the pharmaceutical industry today is in many respects quite different from what it used to be only fifteen years ago. There have been dramatic changes in approaches for identifying new chemical entities with a desired biological activity. While chemical modification of existing leads was the most important approach in the 1970s and 1980s, high-throughput screening and structure-based design are now major players among a multitude of methods used in drug discov ery. Quite often, companies favor one of these relatively new approaches over the other, e.g., screening over rational design, or vice versa, but we believe that an intelligent and concerted use of several or all methods currently available to drug discovery will be more successful in the medium term. What has changed most significantly in the past few years is the time available for identifying new chemical entities. Because of the high costs of drug discovery projects, pressure for maximum success in the shortest possible time is higher than ever. In addition, the multidisciplinary character of the field is much more pronounced today than it used to be. As a consequence, researchers and project managers in the pharmaceutical industry should have a solid knowledge of the more important methods available to drug discovery, because it is the rapidly and intelligently combined use of these which will determine the success or failure of preclinical projects.
Remington Springer Science & Business Media
"Polymorphism in the Pharmaceutical Industry - Solid Form and Drug Development" highlights the relevance of polymorphism in modern pharmaceutical chemistry, with a focus on quality by design (QbD) concepts. It covers all important issues by way of case studies, ranging from properties and crystallization, via thermodynamics, analytics and theoretical modelling right up to patent issues. As such, the book underscores the importance of solid-state chemistry within chemical and pharmaceutical development. It emphasizes why solid-state issues are important, the approaches needed to avoid problems and the opportunities offered by solid-state properties. The authors include true polymorphs as well as solvates and hydrates, while providing information on physicochemical properties, crystallization thermodynamics, quantum-mechanical modelling, and up-scaling. Important analytical tools to characterize solid-state forms and to quantify mixtures are summarized, and case studies on solid-state development processes in industry are also provided. Written by acknowledged experts in the field, this is a high-quality reference for researchers, project managers and quality assurance managers in pharmaceutical, agrochemical and fine chemical companies as well as for academics and newcomers to organic solid-state chemistry.
Pharmaceutical Crystals John Wiley & Sons
New edition of succesful standard reference book for thepharmaceutical industry and pharmaceutical physicians! The Textbook of Pharmaceutical Medicine is the coursebookfor the Diploma in Pharmaceutical Medicine, and is used as astandard reference throughout the pharmaceutical industry. The newedition includes greater coverage of good clinical practice, acompletely revised statistics chapter, and more on safety. Coversthe course information for the Diploma in PharmaceuticalMedicine Fully updated, with new authors Greater coverage of good clinical practice and safety New chapters on regulation of medical devices in Europe andregulation of therapeutic products in Australia
The Magnesium Stearate Handbook iUniverse
Crystallization is an important separation and purification process used in industries ranging from bulk commodity chemicals to specialty chemicals and pharmaceuticals. In recent years, a number of environmental applications have also come to rely on crystallization in waste treatment and recycling processes. The authors provide an introduction to the field of newcomers and a reference to those involved in the various aspects of industrial crystallization. It is a complete volume covering all aspects of industrial crystallization, including material related to both fundamentals and applications. This new edition presents detailed material on crystallization of biomolecules, precipitation, impurity-crystal interactions, solubility, and design. Provides an ideal introduction for industrial crystallization newcomers Serves as a worthwhile reference to anyone involved in the field Covers all aspects of industrial crystallization in a single, complete volume
The Encyclopaedia Britannica Butterworth-Heinemann
This resource provides thorough coverage of pharmacogenetics and its impact on pharmaceuticals, therapeutics, and clinical practice. It opens with the basics of pharmacogenetics, including drug disposition and pharmacodynamics. The following section moves into specific disease areas, including cardiovascular, psychiatry, cancer, asthma/COPD, adverse drug reactions, transplantation, inflammatory bowel disease, and pain medication. Clinical practice and ethical issues make up the third section, with the fourth devoted to technologies like genotyping, genomics, and proteomics. In the fifth part, chapters discuss the impact of key regulatory issues on the pharmaceutical industry.
HPLC for Pharmaceutical Scientists Oxford University Press
"Pharmaceutics is the art of pharmaceutical preparations. It encompasses design of drugs, their manufacture and the elimination of micro-organisms from the products. This book encompasses all of these areas."--Provided by publisher.

Polymorphism Springer Science & Business Media
From crystal structure prediction to totally empirical screening, the quest for new crystal forms has become one of the most challenging issues in the solid state science and particularly in the pharmaceutical world. In this context, multi-component crystalline materials like co-crystals have received renewed interest as they offer the prospect of optimized physical properties. As illustrated in this first book_ entirely dedicated to this emerging class of pharmaceutical compounds_ the outcome of such endeavours into crystal engineering have demonstrated clear impacts on production, marketing and intellectual property protection of active pharmaceutical ingredients (APIs). Indeed, co-crystallization influences relevant physico-chemical parameters (such as solubility, dissolution rate, chemical stability, melting point, hygroscopicity, à) and often offers solids with properties superior to those of the free drug. Combining both reports of the latest research and comprehensive overviews of basic principles, with contributions from selected experts in both academia and industry, this unique book is an essential reference, ideal for pharmaceutical development scientists and graduate students in pharmaceutical science.
Polymorphism in Molecular Crystals 2e John Wiley & Sons
A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition: Contains 30new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying Presents updated and expanded example calculations Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industryf ocuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.
Control and Prediction of Solid-State of Pharmaceuticals John Wiley & Sons
Microscopy plays an integral role in the research and development of new medicines. Pharmaceutical Microscopy describes a wide variety of techniques together with numerous practical applications of importance in drug development. The first section presents general methods and applications with an emphasis on the physical science aspects. Techniques covered include optical crystallography, thermal microscopy, scanning electron microscopy, energy dispersive x-ray spectrometry, microspectroscopy (infrared and Raman), and particle size and shape by image analysis. The second section presents applications of these techniques to specific topics of pharmaceutical interest, including studies of polymorphism, particle size and shape analysis, and contaminant identification. Pharmaceutical Microscopy is designed for those scientists who must use these techniques to solve pharmaceutical problems but do not need to become expert microscopists. Consequently, each section has exercises designed to teach the reader how to use and apply the techniques in the book. Although the focus is on pharmaceutical development, workers in other fields such as food science and organic chemistry will also benefit from the discussion of techniques and the exercises. Provides comprehensive coverage of key microscopy techniques used in pharmaceutical development Helps the reader to solve specific problems in pharmaceutical quality assurance Oriented and designed for pharmaceutical scientists who need to use microscopy but are not expert microscopists Includes a large number of practical exercises to give the reader hands-on experience with the techniques Written by an author with 21 years of experience in the pharmaceutical industry
Pharmaceutical Microscopy Academic Press
This timely reference discusses mass spectrometry in drug metabolism and pharmacokinetic studies. With contributions by professionals from the pharmaceutical industry, this book begins with a review of current mass spectrometry techniques and applications, followed by discussions of various methods for using MS in drug metabolism studies and pharmacokinetics. Highlighting the critical importance of ADME studies for understanding how a drug is absorbed, distributed, metabolized, and excreted by the body, the book s focuses on the use of LC/MS and MALDI-MS. This is a valuable reference for scientists in the pharmaceutical industry, medicine, academia, and even those working in homeland defense.
Mass Spectrometry in Drug Metabolism and Pharmacokinetics Springer
This open access book analyses intellectual property codification and innovation governance in the development of six key industries in India and China. These industries are reflective of the innovation and economic development of the two economies, or of vital importance to them: the IT Industry; the film industry; the pharmaceutical industry; plant varieties and food security; the automobile industry; and peer production and the sharing economy. The analysis extends beyond the domain of IP law, and includes economics and policy analysis. The overarching concern that cuts through all chapters is an inquiry into why certain industries have developed in one country and not in the other, including: the role that state innovation policy and/or IP policy played in such development; the nature of the state innovation policy/IP policy; and whether such policy has been causal, facilitating, crippling, co-relational, or simply irrelevant. The book asks what India and China can learn from each other, and whether there is any possibility of synergy. The book provides a real-life understanding of how IP laws interact with innovation and economic development in the six selected economic sectors in China and India. The reader can also draw lessons from the success or failure of these sectors.
Hot-Melt Extrusion John Wiley & Sons
The pharmaceutical industry is under increasing pressure to do more with less. Drug discovery, development, and clinical trial costs remain high and are subject to rampant inflation. Ever greater regulatory compliance forces manufacturing costs to rise despite social demands for more affordable health care. Traditional methodologies are failing and the industry needs to find new and innovative approaches for everything it does. Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics is the first book to focus on the building blocks of understanding and reducing variation using the Six Sigma method as applied specifically to the pharmaceutical industry. It introduces the fundamentals of Six Sigma, examines control chart theory and practice, and explains the concept of variation management and reduction. Describing the approaches and techniques responsible for their own significant success, the authors provide more than just a set of tools, but the basis of a complete operating philosophy. Allowing other references to cover the structural elements of Six Sigma, this book focuses on core concepts and their implementation to improve the existing products and processes in the pharmaceutical industry. The first half of the book uses simple models and descriptions of practical experiments to lay out a conceptual framework for understanding variation, while the second half introduces control chart theory and practice. Using case studies and statistics, the book illustrates the concepts and explains their application to actual workplace improvements. Designed primarily for the pharmaceutical industry, Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics provides the fundamentals of variation management and reduction in sufficient detail to assist in transforming established methodologies into new and efficient techniques.
Handbook of Pharmaceutical Analysis Elsevier Health Sciences
"Presents a comprehensive examination of polymorphic behavior in pharmaceutical development-demonstrating with clear, practical examples how to navigate complicated crystal structures. Edited by the recipient of the American Association of Pharmaceutical Scientists' 1998 Research Achievement Award in Analysis and Pharmaceutical Quality."