Polymorphism In The Pharmaceutical Industry

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Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations - Sheila Annie Peters 2012-02-17 The only book dedicated to physiologically-based pharmacokineticmodeling in pharmaceutical science

Physiologically-based pharmacokinetic (PBPK) modeling has becomeincreasingly widespread within the pharmaceutical industry over thelast decade, but without one dedicated book that provides

theinformation researchers need to learn these new techniques, itsapplications are severely limited. Describing the principles,methods, and applications of PBPK modeling as used inpharmaceutics, Physiologically-Based Pharmacokinetic (PBPK)Modeling and Simulations fills this void. Connecting theory with practice, the book explores theincredible potential of PBPK modeling for improving drug discoveryand development. Comprised of two parts, the book first provides adetailed and systematic treatment of the principles behindphysiological modeling of pharmacokinetic processes,inter-individual variability, and drug interactions for smallmolecule drugs and biologics. The second part looks in greaterdetail at the powerful applications of PBPK to drug research. Designed for a wide audience encompassing readers looking for abrief overview of the field as well as those who need more detail,the book includes a range of important learning aids. Featuringend-of-chapter keywords for easy reference—a valuable assetfor general or novice readers without a PBPK background—alongwith an extensive bibliography for those looking for furtherinformation, Physiologically- Based Pharmacokinetic (PBPK) Modelingand Simulations is the essential single-volume text on one of thehottest topics in the pharmaceutical sciences today.

Preformulation in Solid Dosage Form Development - Moji Christianah Adeyeye 2008-01-07

During the onset of any clinical trial there are many factors and variables to consider. Funding, time restraints, and regulatory agency guidelines are factors that often influence which variables will be studied, leaving other important information out of the study. Preformulation in Solid Dosage Form Development covers every topic of critical importance to the preformulation stages of drug

development. Serving as a handbook or stand-alone reference, this text equips those in academia and the pharmaceutical industry with both basic and applied principles for the characterization of drugs, excipients, and products, and deals with the issues relating to predictability, identification, and product development during preformulation stages through Phase I of clinical trials. With contributions from an international panel of experts in the field, this guide: outlines an updated preformulation program for modern drug development issues that includes particle morphology, characterization, thermal analysis, and solubility methods contains rational designs for the structure of formulation studies covers the importance of preformulation design using artificial neural networks and computational prediction techniques, and examines the concepts of preliminary-preformulation discusses the typical drug-excipient interactions that could occur during the course of development and methods of characterization includes novel methods to determine the physical and chemical stability of new formulations reviews the structure, content, and format of the preformulation report examines the significance of drug substance physiochemical properties, in regulatory quality by design

Solid State Development and Processing of Pharmaceutical Molecules - Michael Gruss 2021-11-15

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.

Control and Prediction of Solid-State of Pharmaceuticals - Rajni Miglani Bhardwaj 2016-02-02 This thesis investigates a range of experimental and computational approaches for the discovery of solid forms. Furthermore, we gain, as readers, a better understanding of the key factors underpinning solid-structure and diversity. A major part of this thesis highlights experimental work carried out on two structurally very similar compounds. Another important section involves looking at the

influence of small changes in structure and substituents on solid-structure and diversity using computational tools including crystal structure prediction, PIXEL calculations, Xpac, Mercury and statistical modeling tools. In addition, the author presents a fast validated method for solid-state form screening using Raman microscopy on multi-well plates to explore the experimental crystallization space. This thesis illustrates an inexpensive, practical and accurate way to predict the crystallizability of organic compounds based on molecular structure alone, and additionally highlights the molecular factors that inhibit or promote crystallization.

Pharmaceutical Quality by Design - Sarwar Beg 2019-03-27

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and

researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

Chemical Engineering in the Pharmaceutical Industry - Mary T. am Ende 2019-04-08 A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product

manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

The Handbook of Continuous Crystallization - Nima Yazdanpanah 2019-06-19 Continuous crystallization is an area of intense research, with particular respect to the pharmaceutical industry and fine chemicals. Improvements in continuous crystallization technologies offer chemical industries significant financial gains, through reduced expenditure and operational costs, and consistent product quality. Written by well-known leaders in the field, The Handbook of Continuous Crystallization presents fundamental and applied knowledge, with attention paid to application and scaling up, and the burgeoning area of process intensification. Beginning with concepts around crystallization techniques and control strategies, the reader will learn about experimental methods and computational tools. Case studies spanning fine and bulk chemicals, the pharmaceutical

industry, and employing new mathematical tools, put theory into context. With regulatory considerations also covered, this book is a must-have guide for the field.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2019-05-29
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensusbuilding process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating ventilation and air-conditioning systems (HVAC) ? illustrative part; Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

Dosage Form Design Considerations - 2018-07-28
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

Molecular Modelling - Peter Bladon 2019-05-02

This book is a practical, easy to use guide for readers with limited experience of molecular modelling. It will provide students at the undergraduate and early postgraduate chemistry level with a similar entry to modelling. The needs of independent readers are catered for by the inclusion of instructions for acquiring and setting up a suitable computer. Unlike many other textbooks in this field, the authors avoid extensive discussion around complex mathematical foundations behind the methods, choosing instead to provide the reader with the choice of methods themselves. To further these aims of the book, compact discs are included that provide a comprehensive suite of modelling software and datasets. The continuing interest of the pharmaceutical industry in molecular modelling in early stage drug design is recognized by the

inclusion of chapters Medicinal Chemistry and Drug Discovery. There is a chapter on modelling of the solid state, a subject that is also of importance for pharma, where problems due to polymorphism in the crystalline forms of drugs are often encountered in the later design stages.

Aulton's Pharmaceutics - Michael E. Aulton 2013

"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.

Handbook of Pharmaceutical Salts Properties, Selection, and Use - P. Heinrich Stahl 2008-08-04

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.

Solid-state Chemistry of Drugs - Stephen R. Byrn 1999

Pharmaceutical Microscopy - Robert Allen Carlton 2011-05-04

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 Lifecycle Management - Tony Ellery 2012-06-05

A comprehensive guide to optimizing the lifecycle management of pharmaceutical brands The mounting challenges posed by cost containment policies and the prevalence of generic alternatives make optimizing the lifecycle management (LCM) of brand drugs essential for pharmaceutical companies looking to maximize the value of their products. Demonstrating how different measures can be combined to create winning strategies, Pharmaceutical Lifecycle

Management: Making the Most of Each and Every Brand explores this increasingly important field to help readers understand what they can—and must—do to get the most out of their brands. Offering a truly immersive introduction to LCM options for pharmaceuticals, the book incorporates numerous real-life case studies that demonstrate successful and failed lifecycle management initiatives, explaining the key takeaway of each example. Filled with practical information on the process of actually writing and presenting an LCM plan, as well as how to link corporate, portfolio, and individual brand strategies, the book also offers a look ahead to predict which LCM strategies will continue to be effective in the future. While the development of new drugs designed to address unmet patient needs remains the single most important goal of any pharmaceutical company, effective LCM is invaluable for getting the greatest possible value from existing brands. Pharmaceutical Lifecycle Management walks you through the process step by step, making it indispensable reading for pharmaceutical executives and managers, as well as anyone working in the fields of drug research, development, and regulation.

Advances in Organic Crystal Chemistry - Rui Tamura 2015-08-06

For the last decade, the topics of organic crystal chemistry have become diversified, and each topic has been substantially advanced in concert with the rapid development of various analytical and measurement techniques for solid-state organic materials. The aim of this book is to systematically summarize and record the recent notable advances in various topics of organic crystal chemistry involving liquid crystals and organic–inorganic hybrid materials that have been achieved mainly in the last 5 years or so. The authors are invited members of the Division of Organic Crystals, The Chemical Society of Japan

(CSJ), and prominent invited experts from abroad. This edited volume is planned to be published periodically, at least every 5 years, with contributions by prominent authors in Japan and from abroad.

Genetic Polymorphisms - Narasimha Reddy Parine 2017-09-06

The objective of this Genetic Polymorphisms book is to rehighlight and provide few updates on the role of genetic polymorphisms in medicine and agriculture, which void emerging opinion on "full death" of genetic polymorphisms as useful genetic markers. Chapters presented here demonstrate the future benefit of SNPs in many genetic studies as well as prognosis disease and diagnosis.

Developing Solid Oral Dosage Forms - Yihong Qiu 2009-03-10

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

Polymorphism in the Pharmaceutical Industry - Rolf Hilfiker 2019-01-04

"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 - Tong Li 2018-10-16

An important resource that puts the focus on understanding and handling of organic crystals in drug development Since a majority of pharmaceutical solid-state materials are organic crystals, their handling and processing are critical aspects of drug development. Pharmaceutical Crystals: Science and Engineering offers an introduction to and thorough coverage of organic crystals, and explores the essential role they play in drug development and manufacturing. Written contributions from leading researchers and practitioners in the field, this vital resource provides the fundamental knowledge and explains the connection between pharmaceutically relevant properties and the structure of a crystal. Comprehensive in scope, the text covers a range of topics including: crystallization, molecular interactions, polymorphism, analytical methods, processing, and chemical stability. The authors clearly show how to find solutions for pharmaceutical form selection and crystallization processes. Designed to be an accessible guide, this book represents a valuable resource for improving the drug development process of small drug molecules. This important text: Includes the most important aspects of solid-state organic chemistry and its role in drug development Offers solutions for pharmaceutical form selection and crystallization processes Contains a balance between the scientific fundamental and pharmaceutical applications Presents coverage of crystallography, molecular interactions, polymorphism, analytical methods, processing, and chemical stability Written for both practicing

pharmaceutical scientists, engineers, and senior undergraduate and graduate students studying pharmaceutical solid-state materials, Pharmaceutical Crystals: Science and Engineering is a reference and textbook for understanding, producing, analyzing, and designing organic crystals which is an imperative skill to master for anyone working in the field.

Blockbuster Drugs - Jie Jack Li 2014

"This book uses the cases of several landmark drugs to discuss the history of the pharmaceutical industry, and discusses what could be next"--Provided by publisher.

Handbook of Pharmaceutical Granulation Technology - Dilip M. Parikh 2016-04-19

The Third Edition presents all pharmaceutical industry personnel and those in academia with critical updates on the recent advances in granulation technology and changes in FDA regulatory guidelines. Addressing precisely how these recent innovations and revisions affect unit operation of particle generation and granulation, this text assists the re

The Magnesium Stearate Handbook - Patrick C. Okoye 2016-11-18

Magnesium stearate (MgSt) is widely used in cosmetic, food, and pharmaceutical formulations as lubricant in capsule and tablet manufacture at concentrations between 0.25% and 5%. A recent review of the top two hundred prescription drugs showed over 50% contained magnesium stearate. This book covered a broad spectrum of concentration from 1% to 10% for the purpose of presenting their unique properties during powder rheology, tableting, and effect on drug dissolution. MgSt also has both scientifi c and economic signifi cance, given its wide application in global pharmaceutical manufacturing. An understanding of polymorphism (or pseudopolymorphism) in magnesium stearate and the impact on tablet lubrication

process and drug dissolution would provide a valuable tool to pharmaceutical scientists during excipient selection process for new product development and even during reformulation of existing products. Preformulation scientists spend a great deal of time reviewing excipients for new product development both in silico and on the bench. As a result, accurate selection of excipients, such as lubricants, could avoid potential issues with clinical batches, product scale-up, and product transfer during commercialization.

Solid State Characterization of Pharmaceuticals - Richard A. Storey 2011-03-31

The field of solid state characterization is central to the pharmaceutical industry, as drug products are, in an overwhelming number of cases, produced as solid materials. Selection of the optimum solid form is a critical aspect of the development of pharmaceutical compounds, due to their ability to exist in more than one form or crystal structure (polymorphism). These polymorphs exhibit different physical properties which can affect their biopharmaceutical properties. This book provides an up-to-date review of the current techniques used to characterize pharmaceutical solids. Ensuring balanced, practical coverage with industrial relevance, it covers a range of key applications in the field. The following topics are included: Physical properties and processes Thermodynamics Intellectual guidance X-ray diffraction Spectroscopy Microscopy Particle sizing Mechanical properties Vapour sorption Thermal analysis & Calorimetry Polymorph prediction Form selection

Polymorphism in Pharmaceutical Solids - Harry G. Brittain 1999-03-03

"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."

Handbook of Industrial Crystallization - Allan Myerson 2002-01-08

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

Innovation, Economic Development, and Intellectual Property in India and China - Kung-Chung Liu 2019-09-06

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.

Multi-Component Crystals - Edward Tiekink 2017-11-20

In this volume, contributions covering the theoretical and practical aspects of multicomponent crystals provide a timely and contemporary overview of the state-of-the art of this vital aspect of crystal engineering/materials science. With a solid foundation in fundamentals, multi-component crystals can be formed, for example, to enhance pharmaceutical properties of drugs, for the specific control of optical responses to external stimuli and to assemble molecules to allow chemical reactions that are generally intractable following conventional methods. Contents Pharmaceutical co-crystals: crystal engineering and applications Pharmaceutical multi-component crystals: improving the efficacy of anti-tuberculous agents Qualitative and quantitative crystal engineering of multi-functional co-crystals Control of photochromism in N-salicylideneaniline by crystal engineering Quinoline derivatives for multi-component crystals: principles and applications N-oxides in multi-component crystals and in bottom-up synthesis and applications Multi-component crystals and non-ambient conditions Co-crystals for solid-state reactivity and thermal expansion Solution co-

crystallisation and its applications The salt-co-crystal continuum in halogen-bonded systems Large horizontal displacements of benzene-benzene stacking interactions in co-crystals Simultaneous halogen and hydrogen bonding to carbonyl and thiocarbonylfunctionality Crystal chemistry of the isomeric N,N′-bis(pyridin-n-ylmethyl)-ethanediamides, n = 2, 3 or 4 Solute□solvent interactions mediated by main group element (lone-pair)□□□π(aryl) interactions

Polymorphism in Pharmaceutical Solids - Harry G. Brittain 2018-11-12

Using clear and practical examples, Polymorphism of Pharmaceutical Solids, Second Edition presents a comprehensive examination of polymorphic behavior in pharmaceutical development that is ideal for pharmaceutical development scientists and graduate students in pharmaceutical science. This edition focuses on pharmaceutical aspects of polymorphism a

Chemical Engineering in the Pharmaceutical Industry - David J. am Ende 2019-04-23

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.

Remington - Adeboye Adejare 2020-11-03

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

Polymorphism in Molecular Crystals 2e - Joel Bernstein 2020-05-14

Most people are familiar with the fact that diamond and graphite are both composed only of carbon; yet they have very different properties which result from the very different structures of the two solids - they are polymorphs of carbon. Understanding the relationship between the structures and the properties of materials is of fundamental importance in developing and producing new materials with improved or new properties. The existence of polymorphic systems allows the direct study of the connection between structures and properties. This book provides grounding on the fundamental structural and

energetic basis for polymorphism, the preparation and characterization of polymorphic substances and its importance in the specific areas of pharmaceuticals, pigments and high energy (explosive) materials. The closing chapter describes the intellectual property implications and some of the precedent patent litigations in which polymorphism has played a central role. The book contains over 2500 references to provide a ready entry into the relevant literature.

Dosage Form Design Parameters - 2018-07-25

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

Guidance for industry - 2007

Polymorphism in the

Pharmaceutical Industry - Rolf Hilfiker 2019-04-29
"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.
Crystallization of Lipids - Kiyotaka Sato 2018-04-23
An authoritative reference that contains the most up-to-date information knowledge, approaches, and applications of lipid crystals Crystallization of Lipids is a comprehensive resource that offers the most current and emerging knowledge, techniques and applications of lipid crystals. With contributions from noted experts in the field, the text covers the basic research of polymorphic structures, molecular interactions, nucleation and crystal growth

and crystal network formation of lipid crystals which comprise main functional materials employed in food, cosmetic and pharmaceutical industry. The authors highlight trans-fat alternative and saturated-fat reduction technology to lipid crystallization. These two issues are the most significant challenges in the edible-application technology of lipids, and a key solution is lipid crystallization. The text focuses on the crystallization processes of lipids under various external influences of thermal fluctuation, ultrasound irradiation, shear, emulsification and additives. Designed to be practical, the book's information can be applied to realistic applications of lipids to foods, cosmetic and pharmaceuticals. This authoritative and up-to-date guide: Highlights cutting-edge research tools designed to help analyse lipid crystallization with the most current and the conventional techniques Offers a thorough review of the information, techniques and applications of lipid crystals Includes contributions from noted experts in the field of lipid crystals Presents cutting-edge information on the topics of trans-fat alterative and saturated-fat reduction technology Written for research and development technologists as well as academics, this important resource contains research on lipid crystals which comprise the main functional materials employed in food, cosmetic and pharmaceutical industry.

Organic Solid State Chemistry - Gautam R. Desiraju 1987

With the growing recognition that many organic reactions may be conducted easily in the solid state and that organic solids may have unique optical/electronic properties, there has been much interest - in both academia and industry - in the subject of organic solid state chemistry. This book provides, for the first time, a coherent, unified view of the subject. It describes the packing of molecular crystals and how this packing influences chemical reactions

in the solid state. It is concerned with various means of studying the chemistry and physics of molecules in constrained environments. Both experimental and theoretical approaches are discussed. Finally, it tackles the question of prediction of crystal packing, or crystal engineering'. The strength of the book lies in the twin approach adopted, namely that both conceptual and comprehensive chapters are present, in almost equal numbers.

Polymorphism - Rolf Hilfiker 2006-08-21

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.

Modern Pharmaceutical Industry - Thomas M. Jacobsen 2010-10-25

Modern Pharmaceutical Industry: A Primer comprehensively explains the broad range of divisions in the complex pharmaceutical industry. Experts actively involved in each component discuss their own contribution to a pharmaceutical company's work and success. Divisions include regulatory affairs, research and development, intellectual property, pricing, marketing, generics, OTC, and more. The seventeen chapters included in this resource offer a wide range of topics, from discovery and formulation to post-approval and legal. Readers will be given a detailed look at the structure of a contemporary drug company

and a thorough understanding of what goes on behind the scenes. Modern Pharmaceutical Industry: A Primer is a valuable resource for all pharmacy students, new hires at pharmaceutical companies, drug company management, and academic health center libraries. No other text provides a comprehensive look at one of the most dynamic industries related to the modern healthcare system.

Polymorphism in Molecular Crystals - Joel Bernstein 2002

Polymorphism - the multiplicity of structures or forms - is a term that is used in many disciplines. In chemistry it refers to the existence of more than one crystal structure for a particular chemical substance. The properties of a substance are determined by its composition and by its structure. In the last two decades, there has been a sharp rise in the interest in polymorphic systems, as an intrinsically interesting phenomenon and as an increasingly important component in the development and marketing of a variety of materials based on organic molecules (e.g. pharmaceuticals, dyes and pigments, explosives, etc.). This book summarizes and brings up to date the current knowledge and understanding of polymorphism of molecular crystals, and concentrates it in one comprehensive source. The book will be an invaluable reference for students, researchers, and professionals in the field.