Polymorphism In The Pharmaceutical Industry

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
This unique book focuses on the currently 'hot topic' of Pharmaceutical Salts and Co-crystals. Combining both reports of the latest academic research and comprehensive overviews of basic principles, with more applied contributions from selected experts in industry.
Pharmacogenomics: Challenges and Opportunities in Therapeutic Implementation, Second Edition, provides comprehensive coverage of the challenges and opportunities facing the therapeutic implications of pharmacogenomics from academic, regulatory, pharmaceutical, socio-ethical and economic perspectives. While emphasis is on the limitations in moving the science into drug development and direct therapeutic applications, this book also focuses on clinical areas with successful applications and important initiatives that have the ability to further advance the discipline. New chapters cover important topics such as pharmacogenomic data technologies, clinical testing strategies, cost-effectiveness, and pharmacogenomic education and practice guidelines. The importance of ethnicity is also discussed, which highlights phar,acogenomic diversity across Latin American populations. With chapters written by interdisciplinary experts and insights into the future direction of the field, this book is an indispensable resource for academic and industry scientists, graduate students and clinicians engaged in pharmacogenomics research and therapeutic implementation. Provides viewpoints that focus on the scientific and translational challenges and opportunities associated with advancing the field of pharmacogenomics Highlights progress in both the research and clinical areas of pharmacogenomics, as well as relevant implementation experience, challenges, and perspectives on direct-to-consumer genetic testing Includes, where applicable, discussion points, review questions, and cases for self-assessment purposes and to facilitate in-depth discussion
Polymorphism or variation in DNA sequence can affect individual phenotypes such as color of skin or eyes, susceptibility to diseases, and response to drugs, vaccines, chemicals, and pathogens. Especially, the interfaces between genetics, disease susceptibility, and pharmacogenomics have recently been the subject of intense research activity. This book is a self-contained collection of valuable scholarly papers related to genetic diversity and disease susceptibility, pharmacogenomics, ongoing advances in technology, and analytic methods in this field. The book contains nine chapters that cover the three main topics of genetic polymorphism, genetic diversity, and disease susceptibility and pharmacogenomics. Hence, this book is particularly useful to academics, scientists, physicians, pharmacists, practicing researchers, and postgraduate students whose work relates to genetic polymorphisms.
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
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
Formulation is a key step in the drug design process, where the active drug is combined with other substances that maximise the therapeutic potential, safety and stability of the final medicinal product. Modern formulation science deals with biologics as well as small molecules. Regulatory and quality demands, in addition to advances in processing technologies, result in growing challenges as well as possibilities for the field. Pharmaceutical Formulation provides an up to date source of information for all who wish to

understand the principles and practice of formulation in the drug industry. The book provides an understanding of the links between formulation theory and the practicalities of processing in a commercial environment, giving researchers the knowledge to produce effective pharmaceutical products that can be approved and manufactured. The first chapters introduce readers to different dosage forms, including oral liquid products, topical products and solid dosage forms such as tablets and capsules. Subsequent chapters cover pharmaceutical coatings, controlled release drug delivery and dosage forms designed specifically for paediatric and geriatric patients. The final chapter provides an introduction to the vital role intellectual property plays in drug development. Covering modern processing methods and recent changes in the regulatory and quality demands of the industry, Pharmaceutical Formulation is an essential, up to date resource for students and researchers working in academia and in the pharmaceutical industry.

In this book top experts treat general thermodynamic aspects of crystal fabrication; numerical simulation of industrial growth processes; commercial production of bulk silicon, compound semiconductors, scintillation and oxide crystals; X-ray characterization; and crystal machining. Also, the role of crystal technology for renewable energy and for saving energy is discussed. It will be useful for scientists and engineers involved in crystal and epilayer fabrication as well as for teachers and graduate students in material science, chemical and metallurgical engineering, and micro- and optoelectronics, including nanotechnology.

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.

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.

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.

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

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

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

This book highlights the current state-of-the-art regarding the application of applied crystallographic methodologies for understanding, predicting and controlling the transformation from the molecular to crystalline state with the latter exhibiting pre-defined properties. This philosophy is built around the fundamental principles underpinning the three inter-connected themes of Form (what), Formation (how) and Function (why). Topics covered include: molecular and crystal structure, chirality and ferromagnetism, supramolecular assembly, defects and reactivity, morphology and surface energetics. Approaches for preparing crystals and nano-crystals with novel physical, chemical and mechanical properties include: crystallisation, seeding, phase diagrams, polymorphic control, chiral separation, ultrasonic techniques and mechano-chemistry. The vision is realised through examination of a range of advanced analytical characterisation techniques including in-situ studies. The work is underpinned through an unprecedented structural perspective of molecular features, solid-state packing arrangements and surface energetics as well as in-situ studies. This work will be of interest to researchers, industrialists, intellectual property specialists and policy makers interested in the latest developments in the design and supply of advanced high added-value organic solid-form materials and product composites.

"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."

Solid State Characterization of Pharmaceuticals

Crystallization of Lipids

Developing Solid Oral Dosage Forms

Genetic Diversity and Disease Susceptibility

Pharmacogenomics

Pharmaceutical Microscopy

Preformulation in Solid Dosage Form Development

Control and Prediction of Solid-State of Pharmaceuticals

Applied Preformulation, Product Design, and Regulatory Science

Polymorphism in Molecular Crystals

The Science and Practice of Pharmacy

Challenges and Opportunities in Therapeutic Implementation

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

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.

In nearly all process industries, crystallization is used at some stage as a method of production, purification or recovery of solid materials. In recent years, a number of new applications have also come to rely on crystallization processes such as the crystallization of nano and amorphous materials. The articles in this book have been contributed by some of the most respected researchers in this area and cover the frontier areas of research and developments in crystallization processes. Divided into three sections, this book provides the latest research developments in many aspects of crystallization including the crystallization of biological macromolecules and pharmaceutical compounds, the crystallization of nanomaterials and the crystallization of amorphous and glassy materials. This book is of interest to both fundamental research and practicing scientists and will prove invaluable to all chemical engineers and industrial chemists in process industries, as well as crystallization workers and students in industry and academia.

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.

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.

This 1972 monograph is devoted to the analysis and interpretation of the infrared and Raman spectra of solid compounds, frequently used for their identification and characterization. It was thought unsatisfactory to analyse such spectra by the theory applicable to gas-phase samples, though this was frequently done. Furthermore, the results obtained by far infrared and laser Raman spectrometers, which detect the movement of atoms and/or molecules as a whole, had no gas-phase analogy. A separate approach to solid state vibrational spectra was therefore proposed within this volume. Dr Sherwood describes the solid state physics of vibrational spectroscopy and extends it to the more complex structures of low symmetry. He assumes an understanding of the infrared and Raman spectra of gases.

Recent trends within the pharmaceutical industry through the Quality by Design initiatives have seen a greater emphasis on the development of a molecular-scale understanding in the development of efficient manufacturing processes for active pharmaceutical ingredients (APIs) and their formulation into drug products. This book examines the state-of-the-art computational approaches to guide solid form experiments to optimize the physical and chemical properties of API related to its stability, bioavailability and formulatability. The book is intended to be used as a professional reference to researchers in Pharmaceutical industry and in academia and potentially as a text book reference for undergraduate, graduate and postgraduate students in the field of Computational Chemistry, Solid State Chemistry, Pharmaceutical Science and Material Science.

As a result of the Process Analytical Technologies (PAT) initiative launched by the U.S. Food and Drug Administration (FDA), analytical development is receiving more attention within the pharmaceutical industry. Illustrating the importance of analytical methodologies, Thermal Analysis of Pharmaceuticals presents reliable and versatile charac

Molecular Modelling
Science and Engineering
Remington
Vibrational Spectroscopy of Solids
Polymorphism
Computational Chemistry Demystified
Handbook of Industrial Crystallization
In the Pharmaceutical Industry
Recrystallization in Materials Processing
Computational Pharmaceutical Solid State Chemistry
Thermal Analysis of Pharmaceuticals
The Science and Technology of Dosage Forms

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

The book Recrystallization in Materials Processing shows selected results obtained during the last few years by researchers worked on recrystallization-related issues. These researchers offer their knowledge from a range of scientific disciplines, such as materials science, metallurgy and pharmacology. The authors emphasize that the progress in this particular field of scientific research is possible today due to coordinated efforts of many research groups that work in materials science, chemistry, physics, pharmacology, and other sciences. Thus, it is possible to perform a detailed analysis of the scientific problem. The analysis starts from the selection of appropriate techniques and methods of characterization. It is then combined with the development of new tools in diagnostics, and it finished with physical modeling of phenomena.

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.

"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.

Polymorphism in the Pharmaceutical IndustrySolid Form and Drug DevelopmentJohn Wiley & Sons

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

First book ever printed on growing crystals in a gel medium provides thorough descriptions of the procedure, its history and future potential. "Concise and readable."—Science. 42 illus. 1970 edition.

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 Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

Handbook of Pharmaceutical Salts Properties, Selection, and Use
Fundamentals and Applications in Food, Cosmetics and Pharmaceuticals
Crystal Growth Technology
Drug Product Design, Development, and Modeling
Engineering Crystallography: From Molecule to Crystal to Functional Form
Integrated Pharmaceutics

Modern Pharmaceutical Industry
Organic Solid State Chemistry
Dosage Form Design Considerations
Principles and Applications
Pharmaceutical Theory and Practice

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.

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.

The use of analytical sciences in the discovery, development andmanufacture of pharmaceuticals is wide-ranging. From the analysisof minute amounts of complex biological materials to the qualitycontrol of the final dosage form, the use of analytical technologycovers an immense range of techniques and disciplines. This book concentrates on the analytical aspects of drugdevelopment and manufacture, focusing on the analysis of the activeingredient or drug substance. It provides those joining theindustry or other areas of pharmaceutical research with a source ofreference to a broad range of techniques and their applications,allowing them to choose the most appropriate analytical techniquefor a particular purpose. The volume is directed at analytical chemists, industrialpharmacists, organic chemists, pharmaceutical chemists andbiochemists.

Solid-State Properties of Pharmaceutical Materials -- Contents -- Preface -- Acknowledgments -- 1 Solid-State Properties and Pharmaceutical Development -- 1.1 Introduction -- 1.2 Solid-State Forms -- 1.3 ICH Q6A Decision Trees -- 1.4 "Big Questions" for Drug Development -- 1.5 Accelerating Drug Development -- 1.6 Solid-State Chemistry in Preformulation and Formulation -- 1.7 Learning Before Doing and Quality by Design -- 1.8 Performance and Stability in Pharmaceutical Development -- 1.9 Moisture Uptake -- 1.10 Solid-State Reactions -- 1.11 Noninteracting Formulations: Physical Characterizations -- References -- 2 Polymorphs -- 2.1 Introduction -- 2.2 How Are Polymorphs Formed? -- 2.3 Structural Aspect of Polymorphs -- 2.3.1 Configurational Polymorphs -- 2.3.2 Conformational Polymorphs -- 2.4 Physical, Chemical, and Mechanical Properties -- 2.4.1 Solubility -- 2.4.2 Chemical Stability -- 2.4.3 Mechanical Properties -- 2.5 Thermodynamic Stability of Polymorphs -- 2.5.1 Monotropy and Enantiotropy -- 2.5.2 Burger and Rambergers Rules -- 2.5.3 vant Hoff Plot -- 2.5.4 DG/Temperature Diagram -- 2.6 Polymorph Conversion -- 2.6.1 Solution-Mediated Transformation -- 2.6.2 Solid-State Conversion -- 2.7 Control of Polymorphs -- 2.8 Polymorph Screening -- 2.9 Polymorph Prediction -- References -- 3 Solvates and Hydrates -- 3.1 Introduction -- 3.2 Pharmaceutical Importance of Hydrates -- 3.3 Classification of Pharmaceutical Hydrates -- 3.4 Water Activity -- 3.5 Stoichiometric Hydrates -- 3.6 Nonstoichiometric Hydrates -- 3.7 Hydration/Dehydration -- 3.8 Preparation and Characterization of Hydrates and Solvates -- References -- 4 Pharmaceutical Salts -- 4.1 Introduction -- 4.2 Importance of Pharmaceutical Salts -- 4.3 Weak Acid, Weak Base, and Salt -- 4.4 pH-Solubility Profiles of Ionizable Compounds

Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

For almost a decade, quantitative NMR spectroscopy (qNMR) has been established as valuable tool in drug analysis. In all disciplines, i. e. drug identification, impurity profiling and assay, qNMR can be utilized. Separation techniques such as high performance liquid chromatography, gas chromatography, super fluid chromatography and capillary electrophoresis techniques, govern the purity evaluation of drugs. However, these techniques are not always able to solve the analytical problems often resulting in insufficient methods.

Nevertheless such methods find their way into international pharmacopoeias. Thus, the aim of the book is to describe the possibilities of qNMR in pharmaceutical analysis. Beside the introduction to the physical fundamentals and techniques the principles of the application in drug analysis are described: quality evaluation of drugs, polymer characterization, natural products and corresponding reference compounds, metabolism, and solid phase NMR spectroscopy for the characterization drug substances, e.g. the water content, polymorphism, and drug formulations, e.g. tablets, powders. This part is accompanied by more special chapters dealing with representative examples. They give more detailed information by means of concrete examples. Combines theory, techniques, and concrete applications—all of which closely resemble the laboratory experience Considers international pharmacopoeias, addressing the concern for licensing Features the work of academics and researchers, appealing to a broad readership

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.

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.

Solid Form and Drug Development
Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical Ingredients
Regulations, Methodologies, and Best Practices
Crystal Growth in Gels
Pharmaceutical Formulation
Chemical Engineering in the Pharmaceutical Industry
Pharmaceutical Analysis
Experimental and Computational Approaches