

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

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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

HPLC for Pharmaceutical Scientists is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry. It provides a unified approach to HPLC with an equal and balanced treatment of the theory and practice of HPLC in the pharmaceutical industry. In-depth discussion of retention processes, modern HPLC separation theory, properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation. Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico-chemical point of view are provided. This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development. The latest advancements and trends in hyphenated and specialized HPLC techniques

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(LC-MS, LC-NMR, Preparative HPLC, High temperature HPLC, high pressure liquid chromatography) are also discussed.

"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

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newcomers to organic solid-state chemistry.

Dosage Form Design Parameters, Volume II, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, preformulation 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

A guide to the latest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of

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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

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information on the solid state of active pharmaceutical ingredients for their efficient development and production.

From crystal structure prediction to totally empirical screening, the quest for new crystal forms has become one of the most challenging issues in the solid state science and particularly in the pharmaceutical world. In this context, multi-component crystalline materials like co-crystals have received renewed interest as they offer the prospect of optimized physical properties. As illustrated in this first book_ entirely dedicated to this emerging class of pharmaceutical compounds_ the outcome of such endeavours into crystal engineering have demonstrated clear impacts on production, marketing and intellectual property protection of active pharmaceutical ingredients (APIs). Indeed, co-crystallization influences relevant physico-chemical parameters (such as solubility, dissolution rate, chemical stability, melting point, hygroscopicity, à) and often offers solids with properties superior to those of the free drug. Combining both reports of the latest research and comprehensive overviews of basic principles, with contributions from selected experts in both academia and industry, this unique book is an essential reference, ideal for pharmaceutical development scientists and graduate students in pharmaceutical science.

An important resource that puts the focus on understanding and handling of

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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

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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.

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

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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 alternative 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.

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.

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Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discusses various issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials, mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time

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

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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

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

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stages.

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 or variation in DNA sequence can affect individual phenotypes such as color of

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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. 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. A comprehensive guide to the current research, major challenges, and future prospects of controlled drug delivery systems *Controlled drug delivery* has the potential to significantly improve therapeutic outcomes, increase clinical benefits, and enhance the safety of drugs in a wide range of diseases and health conditions. *Fundamentals of Drug Delivery* provides comprehensive and up-to-date coverage of the essential principles and processes of modern controlled drug delivery systems. Featuring contributions by respected researchers, clinicians,

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and pharmaceutical industry professionals, this edited volume reviews the latest research in the field and addresses the many issues central to the development of effective, controlled drug delivery. Divided in three parts, the book begins by introducing the concept of drug delivery and discussing both challenges and opportunities within the rapidly evolving field. The second section presents an in-depth critique of the common administration routes for controlled drug delivery, including delivery through skin, the lungs, and via ocular, nasal, and otic routes. The concluding section summarizes the current state of the field and examines specific issues in drug delivery and advanced delivery technologies, such as the use of nanotechnology in dermal drug delivery and advanced drug delivery systems for biologics. This authoritative resource: Covers each main stage of the drug development process, including selecting pharmaceutical candidates and evaluating their physicochemical characteristics Describes the role and application of mathematical modelling and the influence of drug transporters in pharmacokinetics and drug disposition Details the physiology and barriers to drug delivery for each administration route Presents a historical perspective and a look into the possible future of advanced drug delivery systems Explores nanotechnology and cell-mediated drug delivery, including applications for targeted delivery and toxicological and safety issues Includes comprehensive references and links to the primary literature Edited by a team of internationally-recognized experts, *Fundamentals of Drug Delivery* is essential reading for researchers, industrial scientists, and advanced students in all areas of drug delivery including pharmaceuticals, pharmaceutical sciences, biomedical engineering, polymer and materials science, and chemical and biochemical engineering.

The only book dedicated to physiologically-based pharmacokinetic modeling in

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pharmaceutical science Physiologically-based pharmacokinetic (PBPK) modeling has become increasingly widespread within the pharmaceutical industry over the last decade, but without one dedicated book that provides the information researchers need to learn these new techniques, its applications are severely limited. Describing the principles, methods, and applications of PBPK modeling as used in pharmaceuticals, Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations fills this void. Connecting theory with practice, the book explores the incredible potential of PBPK modeling for improving drug discovery and development. Comprised of two parts, the book first provides a detailed and systematic treatment of the principles behind physiological modeling of pharmacokinetic processes, inter-individual variability, and drug interactions for small molecule drugs and biologics. The second part looks in greater detail at the powerful applications of PBPK to drug research. Designed for a wide audience encompassing readers looking for a brief overview of the field as well as those who need more detail, the book includes a range of important learning aids. Featuring end-of-chapter keywords for easy reference—a valuable asset for general or novice readers without a PBPK background—along with an extensive bibliography for those looking for further information, Physiologically- Based Pharmacokinetic (PBPK) Modeling and Simulations is the essential single-volume text on one of the hottest topics in the pharmaceutical sciences today.

Using clear and practical examples, Polymorphism of Pharmaceutical Solids, Second

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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

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

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Simultaneous halogen and hydrogen bonding to carbonyl and thiocarbonyl functionality
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) interactions (aryl)

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 pharmaceuticals. 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

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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

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

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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.

Polymorphism in the Pharmaceutical Industry Solid Form and Drug Development John Wiley & Sons

Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in

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drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout. 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

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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.

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 pharmacogenomic 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

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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

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, preformulation 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

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

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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

This book deals with various unique elements in the drug development process within chemical engineering science and pharmaceutical R&D. The book is intended to be used as a professional reference and potentially as a text book reference in pharmaceutical engineering and pharmaceutical sciences. Many of the experimental methods related to pharmaceutical process development are learned on the job. This book is intended to provide many of those important concepts that R&D Engineers and manufacturing Engineers should know and be familiar if they are going to be successful in the Pharmaceutical Industry. These include basic analytics for quantitation of reaction components—often skipped in ChE Reaction Engineering and kinetics books. In addition Chemical Engineering in the Pharmaceutical Industry introduces contemporary methods of data analysis for kinetic modeling and extends these concepts into Quality by Design strategies for regulatory filings. For the current professionals, in-silico process modeling tools that streamline experimental screening approaches is also new and presented here. Continuous flow processing, although mainstream for ChE, is unique in this context given the range of scales and the complex economics associated with transforming existing batch-plant capacity. The book will be split into four distinct yet related parts. These parts will address the fundamentals of analytical

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techniques for engineers, thermodynamic modeling, and finally provides an appendix with common engineering tools and examples of their applications.

In recent years, many factors have combined to change the operating environment of the international pharmaceutical industry leading to greater specialisation and sophistication. This new edition will give an update of the different opportunities in drug discovery and development and the scientific, medical or other specialist training needed to accomplish them. The scope of this edition has been broadened to encompass all major roles, including marketing and sales.

"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."

The use of analytical sciences in the discovery, development and manufacture of pharmaceuticals is wide-ranging. From the analysis of minute amounts of complex biological materials to the quality control of the final dosage form, the use of analytical technology covers an immense range of techniques and disciplines. This book concentrates on the analytical aspects of drug development and manufacture, focusing on the analysis of the active ingredient or drug substance. It provides those joining the industry or other areas of pharmaceutical research with a source of reference to a broad range of techniques and their applications, allowing them to choose the most appropriate analytical technique for a particular purpose. The volume is directed at analytical chemists, industrial pharmacists, organic chemists, pharmaceutical chemists and biochemists.

For almost a decade, quantitative NMR spectroscopy (qNMR) has been established as

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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 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

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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.

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.

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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 30 new 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.

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

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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.

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

Pharmaceutical science deals with the whole spectrum of drug development from start to finish. There are many different facets to the pharmaceutical industry, from initial research to the finished product, including the equipment used, trials performed, and regulations that must be followed. Presenting an overview of all of these different aspects, the *Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition* is a must-have reference guide for all laboratories and libraries in the pharmaceutical field. Bringing together leaders from every specialty related to pharmaceutical science and technology, this is the single-source reference at the forefront of pharmaceutical R&D. The strength of this work is not only its breadth but also the caliber of contributing writers, all experts

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in their field, writing on all aspects of pharmaceutical science and technology. The fourth edition offers 29 new chapters ranging from biomarkers, computational chemistry, and contamination control to high-throughput screening, orally disintegrating tablets, and quality by design. The encyclopedia details best practices of equipment used, methods for manufacturing, options for packaging, and routes for drug delivery. The volumes also provide a thorough understanding of the choices behind each method. In addition, the regulations, safety aspects, patent guidance, and methods of analysis are presented. Key Areas Covered: Analytics Biomarkers Dosage forms Drug delivery Formulation Informatics Manufacturing Packaging Processing Regulatory affairs Systems validation This is an authoritative reference source for those practicing in any area of pharmaceutical science and technology, enabling the pharmaceutical specialist and novice alike to keep abreast of developments in this constantly evolving and highly competitive field. * Online version coming soon. Contact us to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367 / (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062 / (E-mail) online.sales@tandf.co.uk
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