# Polymorphism In Pharmaceutical Solids Drugs And The Pharmaceutical Sciences

Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Edited by the Associate Director of Analytical Research and Development for the American Association of Pharmaceutical Scientists, Analytical Profiles of Drug Substances and Excipients brings this information together in one source. The scope of the series has recently been expanded to include profiles of excipient materials.

Process Analytical Technology explores the concepts of PAT and its application in the chemical and pharmaceutical industry from the point of view of the analytical chemist. In this new edition all of the original chapters have been updated and revised, and new chapters covering the important topics of sampling, NMR, fluorescence, and acoustic chemometrics have been added. Coverage includes: Implementation of Process Analytical Technologies UV-Visible Spectroscopy for On-line Analysis Infrared Spectroscopy for Process Analytical Applications Process Raman Spectroscopy Process NMR Spectrscopy: Technology

and On-line Applications Fluorescent Sensing and Process Analytical Applications Chemometrics in Process Analytical Technology (PAT) On-Line PAT Applications of Spectroscopy in the Pharmaceutical Industry Future Trends for PAT for Increased Process Understanding and Growing Applications in Biomanufacturing NIR Chemical Imaging This volume is an important starting point for anyone wanting to implement PAT and is intended not only to assist a newcomer to the field but also to provide up-to-date information for those who practice process analytical chemistry and PAT. It is relevant for chemists, chemical and process engineers, and analytical chemists working on process development, scale-up and production in the pharmaceutical, fine and specialty chemicals industries, as well as for academic chemistry, chemical engineering, chemometrics and pharmaceutical science research groups focussing on PAT. Review from the First Edition “The book provides an excellent first port of call for anyone seeking material and discussions to understand the area better. It deserves to be found in every library that serves those who are active in the field of Process Analytical Technology.”—Current Engineering Practice 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

Covering every essential element in the development of chiral products, this reference provides a solid overview of the formulation, biopharmaceutical characteristics, and regulatory issues impacting the production of these pharmaceuticals. It supports researchers as they evaluate the pharmacodynamic, pharmacokinetic, and

toxicological characteristics of specific enantiomers and chiral drug compounds and addresses in one convenient reference all the major challenges pertaining to drug chirality that have been neglected in the literature. Chirality in Drug Design and Development collects the latest studies from an interdisciplinary team of experts on chiral drug design.

Pharmaceutical formulations have evolved from simple and traditional systems to more modern and complex novel dosage forms. Formulation development is a tedious process and requires an enormous amount of effort from many different people. Developing a stable novel dosage form and further targeting it to the desired site inside the body has always been a challenge. The purpose of this book is to bring together scholarly articles that highlight recent developments and trends in pharmaceutical formulation science. Each article has been written by authors specializing in the subject area and hailing from top institutions around the world. The book has been written in a systematic and lucid style explaining all basic concepts and fundamentals in a very simple way. This book aims to serve the need of all individuals involved at any level in the pharmaceutical dosage form development. I sincerely hope that the book will be liked by inquisitive students and learned colleagues.

Profiles of Drug Substances, Excipients, and Related Methodology, Volume 42 presents comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and

excipients, thus meeting the needs of the pharmaceutical community and allowing for the development of a timely vehicle for publishing review materials on the topic. This latest release covers a variety of substances, including Cinacalcet Hydrochloride, Clenbuterol Hydrochloride, Gliclazide, Lomefloxacin, Olmesartan, Propranolol, and Tolterodine Tartrate. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories, Physical profiles of drug substances and excipients, Analytical profiles of drug substances and excipients, Drug metabolism and pharmacokinetic profiles of drug substances and excipients, Methodology related to the characterization of drug substances and excipients, Methods of chemical synthesis, and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Contains contributions from leading authorities Informs and updates on all the latest developments in the field

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 contribution book collects reviews and original articles from eminent experts working in the interdisciplinary arena of novel drug delivery systems and their uses. From their direct and recent experience, the readers can achieve a wide vision on the new and ongoing potentialities of different drug delivery systems. Since the advent of analytical techniques and capabilities to measure particle sizes in nanometer ranges, there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery. On the other hand, this reference discusses advances in the design,

optimization, and adaptation of gene delivery systems for the treatment of cancer, cardiovascular, pulmonary, genetic, and infectious diseases, and considers assessment and review procedures involved in the development of gene-based pharmaceuticals.

Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discussesvarious issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials, mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time Scientists have attributed more than 40 percent of the failures in new drug development to poor biopharmaceutical properties, particularly water insolubility. Issues surrounding water insolubility can postpone, or completely derail, important new drug development. Even much-needed reformulation of currently marketed products can be significantly affected by these challenges. Water Insolubility is the Primary Culprit in over 40% of New Drug Development Failures The most comprehensive resource on the topic, this second edition of Water Insoluble Drug Formulation brings

together a distinguished team of experts to provide the scientific background and step-by-step guidance needed to deal with solubility issues in drug development. Twenty-three chapters systematically describe solubility properties and their impact on formulation, from theory to industrial practice. With detailed discussion on how these properties contribute to solubilization and dissolution, the text also features six brand new chapters on water-insoluble drugs, exploring regulatory aspects, pharmacokinetic behavior, early phase formulation strategies, lipid based systems for oral delivery, modified release of insoluble drugs, and scalable manufacturing aspects. The book includes more than 15 water-insoluble drug delivery systems or technologies, illustrated with case studies featuring oral and parenteral applications. Highlighting the most current information and data available, this seminal volume reflects the significant progress that has been made in nearly all aspects of this field.

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

principles, with contributions from selected experts in both academia and industry, this unique book is an essential reference, ideal for pharmaceutical development scientists and graduate students in pharmaceutical science.

Polymorphism - 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.

The crystalline state is the most commonly used essential solid active pharmaceutical ingredient (API). The characterization of pharmaceutical crystals encompasses many scientific disciplines, but the core is crystal structure analysis, which reveals the molecular structure of essential pharmaceutical compounds. Crystal structure analysis provides important structural information related to the API's wide range of physicochemical properties, such as solubility, stability, tablet performance, color, and hygroscopicity. This book entitled “Pharmaceutical Crystals" focuses on the relationship between crystal structure and physicochemical properties. In particular, the new crystal structure of pharmaceutical compounds involving multi-component crystals, such as co-crystals, salts, and hydrates, and

polymorph crystals are reported. Such crystal structures were investigated in the latest studies that combined morphology, spectroscopic, theoretical calculation, and thermal analysis with crystallographic study. This book highlights the importance of crystal structure information in many areas of pharmaceutical science and presents current trends in the structure–property study of pharmaceutical crystals. The Guest Editors of this book hope the readers enjoy a wide variety of recent studies on Pharmaceutical Crystals.

This extensive reference/text explores the principles, instrumentation, processes, and programs of pharmaceutical solid science as well as new aspects on one-component systems, micromeritics, polymorphism, solid-state stability, cohesion, powder flow, blending, single- unit sustained release, and tablet coating. Reveals unique approaches in pharmaceutical solid science not previously published in any other text! Providing current data on crystallization, dissolution from particles and polydisperse populations, powder volumes and densities, comminution, wet granulation, and hard-shell capsules, Advanced Pharmaceutical Solids describes moisture isotherms with crystalline solids documents the effects of moisture on solid-state stability highlights tablet physics and principles explains sustained release by microencapsulation presents prediction equations for solubility in binary solvents discusses particle sizes and diameters identifies Brunauer, Emmett, and Teller Isotherms and more! Considering properties of solids, permeamitry and gas absorption methods, amorphates, and purification by pH-change precipitation, Advanced Pharmaceutical Solids is an essential reference for pharmacists; pharmaceutical scientists; medicinal, physical, surface, colloid, and analytical chemists and biochemists; and an effective text for upper-level undergraduate and graduate students in these disciplines.

This unique reference provides the first systematic coverage available in a single-source volume on the application of materials science techniques to the pharmaceutical field-offering a comprehensive program for the physical characterization of raw materials, drug substances, and formulated products.

This volume is intended to provide the reader with a breadth of understanding regarding the many challenges faced with the formulation of poorly water-soluble drugs as well as in-depth knowledge in the critical areas of development with these compounds. Further, this book is designed to provide practical guidance for overcoming formulation challenges toward the end goal of improving drug therapies with poorly water-soluble drugs. Enhancing solubility via formulation intervention is a unique opportunity in which formulation scientists can enable drug therapies by creating viable medicines from seemingly undeliverable molecules. With the ever increasing number of poorly water-soluble compounds entering development, the role of the formulation scientist is growing in importance. Also, knowledge of the advanced analytical, formulation, and process technologies as well as specific regulatory considerations related to the formulation of these compounds is increasing in value. Ideally, this book will serve as a useful tool in the education of current and future generations of scientists, and in this context contribute toward providing patients with new and better medicines.

Biophysical techniques are used in many key stages of the drug discovery process including in screening for new receptor ligands, in characterising drug mechanisms, and in validating data from biochemical and cellular assays. This book provides an overview of the biophysical methods applied in drug discovery today, including traditional techniques and newer developments. Perspectives from academia and industry across a spectrum of techniques are

brought together in a single volume. Small and biotherapeutic approaches are covered and strengths and limitations of each technique are presented. Case studies illustrate the application of each technique in real applied examples. Finally, the book covers recent developments in areas such as electron microscopy with discussions of their possible impact on future drug discovery. This is a go-to volume for biophysicists, analytical chemists and medicinal chemists providing a broad overview of techniques of contemporary interest in drug discovery.

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

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.

Providing a roadmap from early to late stages of drug development, this book overviews amorphous solid dispersion technology – a leading platform to deliver poorly water soluble drugs, a major hurdle in today's pharmaceutical industry. • Helps readers understand amorphous solid dispersions and apply techniques to particular pharmaceutical systems • Covers physical and chemical properties, screening, scale-up, formulation, drug product manufacture, intellectual property, and regulatory considerations • Has an appendix with structure and property information for polymers commonly used in drug development and with marketed drugs developed using the amorphous sold dispersion approach • Addresses global regulatory issues including USA regulations, ICH guidelines, and patent concerns around the world

"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." Teaches future and current drug developers the latest innovations in drug formulation design and optimization This highly accessible, practice-oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies, including the use of functional excipients to enhance solubility and stability. It covers oral, intravenous, topical, and parenteral administration routes. The book also discusses safety aspects of drugs and excipients, as well as regulatory issues relevant to formulation. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development. It then offers readers reliable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. -Provides information that is essential for the drug development effort -Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and cocrystals -Describes current approaches in early pre-formulation to achieve the best in

vivo results -Addresses regulatory and safety aspects, which are key considerations for pharmaceutical companies -Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative Dosage Forms: Design and Development at Early Stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists, pharmaceutical chemists, and pharmacologists.

"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 Pharmaceutical SolidsCRC Press

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.

A guide to the latest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain. The authors—noted experts on the topic—examine the importance of the solid state form of chemical and biological drugs and review the

development, production, quality control, formulation, and stability of medicines. The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality. It also includes information on relevant regulatory and intellectual property considerations. This resource is aimed at professionals in the pharmaceutical industry and offers an in-depth examination of the commercially relevant issues facing developers, producers and distributors of drug substances. This important book: Provides a guide for the effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation, process control, and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists, pharmaceutical industry professionals, pharma engineers, solid state chemists, chemical engineers, Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production. Amorphous solid dispersion (ASD) is a powerful formulation technology to improve oral absorption of

poorly soluble drugs. Despite their being in existence for more than half a century, controlling ASD performance is still regarded as difficult because of ASD's natural non-equilibrium. However, recent significant advances in ASD knowledge and technology may enable a much broader use of ASD technology. This Special Issue, which includes 3 reviews and 6 original articles, focuses on recent progresses in ASD technology in hopes of helping to accelerate developmental studies in the pharmaceutical industry. In striving for a deep understanding of ASD non-equilibrium behavior, the Special issue also delves into and makes progress in the theory of soft-matter dynamics.

This book explains theoretical and technological aspects of amorphous drug formulations. It is intended for all those wishing to increase their knowledge in the field of amorphous pharmaceuticals. Conversion of crystalline material into the amorphous state, as described in this book, is a way to overcome limited water solubility of drug formulations, in this way enhancing the chemical activity and bioavailability inside the body. Written by experts from various fields and backgrounds, the book introduces to fundamental physical aspects (explaining differences between the ordered and the disordered solid states, the enhancement of solubility resulting from drugs amorphization, physical instability and how it can be overcome) as

well as preparation and formulation procedures to produce and stabilize amorphous pharmaceuticals. Readers will thus gain a well-funded understanding and find a multi-faceted discussion of the properties and advantages of amorphous drugs and of the challenges in producing and stabilizing them. The book is an ideal source of information for researchers and students as well as professionals engaged in research and development of amorphous pharmaceutical products.

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

oxides in multi-component crystals and in bottom-up synthesis and applications Multi-component crystals and non-ambient conditions Co-crystals for solid-state reactivity and thermal expansion Solution co-crystallisation and its applications The salt-co-crystal continuum in halogen-bonded systems Large horizontal displacements of benzene-benzene stacking interactions in co-crystals Simultaneous halogen and hydrogen bonding to carbonyl and thiocarbonylfunctionality Crystal chemistry of the isomeric N,N'-bis(pyridin-n-ylmethyl)-ethanediamides, n = 2, 3 or 4 Solute?solvent interactions mediated by main group element (lone-pair)????(aryl) interactions

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.

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

Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Edited by the Associate Director of Analytical Research and Development for the American Association of Pharmaceutical Scientists, Analytical Profiles of Drug Substances

and Excipients brings this information together into one source. The scope of the series has recently been expanded to include profiles of excipient materials.

Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Presents comprehensive reviews covering all aspects of drug development and formulation of drugs Profiles creatine monohydrate and fexofenadine hydrochloride, as well as five others Meets the information needs of the drug development community

Whilst following in the footsteps of previous volumes by presenting comprehensive reviews of drug substances and additional materials, this title also heralds a significant expansion of the scope of the series. Traditional contributions will now also be augmented by publication of critical review chapters that summarize information related to the characterization of drug substances and excipients. This change is required to better meet the needs of the

pharmaceutical communtiy and to allow the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series will encompass review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. * Presents comprehensive reviews covering all aspects of drug development and formulation of drugs * Now encompassing critical review chapters * Meets the information needs of the drug development community

Profiles of Drug Substances, Excipients, and Related Methodology, Volume 44, presents comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. The series encompasses review articles, with this release focusing on Cefpodoxime proxetil, Levetiracetam, Paclitaxel, Sorafenib, Sucrose octaacetate, Thiouracil, Topiramate, Spectrophotometric analysis, and Cocrystal Systems of Pharmaceutical Interest: 2012-2014. Contains contributions from leading authorities Informs and updates on all the latest developments in the field of drug substances, excipients and methodologies

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 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.

Solvent systems are integral to drug development and pharmaceutical technology. This single topic encompasses numerous allied subjects running the gamut from recrystallization solvents to biorelevant media. The goal of this contribution to the AAPS Biotechnology: Pharmaceutical Aspects series is to generate both a practical handbook as well as a reference allowing the reader to make effective decisions concerning the use of solvents and solvent systems. To this end, the monograph was created by inviting recognized experts from a number of fields to author relevant

sections. Specifically, 15 chapters have been designed covering the theoretical background of solubility, the effect of ionic equilibria and pH on solubilization, the use of solvents to effect drug substance crystallization and polymorph selection, the use of solvent systems in high throughput screening and early discovery, solvent use in preformulation, the use of solvents in bio-relevant dissolution and permeation experiments, solvents and their use as toxicology vehicles, solubilizing media and excipients in oral and parenteral formulation development, specialized vehicles for protein formulation and solvent systems for topical and pulmonary drug administration. The chapters are organized such that useful decision trees are included together with the scientific underpinning for their application. In addition, trends in the use of solvent systems and a balance of current views make this monograph useful to both the novice and experienced researcher and to scientists at all developmental stages from early discovery to late pharmaceutical operations.

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

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