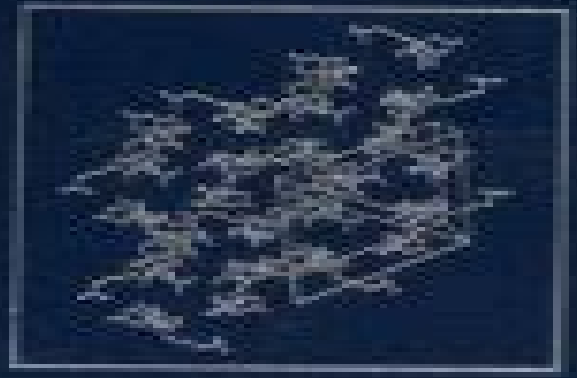
Solid-State Chemistry of Drugs

Stephen R. Byrn



Solid State Chemistry Of Drugs

Steven W. Baertschi,Karen M. Alsante,Robert A. Reed

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Solid-state Chemistry of Drugs Stephen R. Byrn,1999 Solid State Chemistry of Drugs Stephen R. Byrn,1982-01-01

Solid-State Materials in Pharmaceutical Chemistry Stephen R. Byrn,George Zografi,Xiaoming (Sean) Chen,2025-09-30 Updated and expanded information on the properties of pharmaceutical solids and their impact on drug product performance quality and stability Solid State Materials in Pharmaceutical Chemistry provides readers with a comprehensive and up to date resource for understanding and controlling the solid state properties of pharmaceutical materials enabling the development of safe and effective medicines including small molecule compounds peptides proteins and nucleotides This new edition covers the significant transformations in the landscape of pharmaceutical research development and manufacturing since the previous edition was published presenting both novel challenges and unprecedented opportunities New chapters in this edition cover physical and chemical properties of RNA therapeutics a frontier to many life saving medicines and vaccines including Covid vaccines and final stage drug substance manufacturing and control addressing challenges in API process development including impurity purging chiral separation final form preparation particle size reduction and nitrosamine control Readers will also find other updated topics including bulk and surface properties of solids lipid nanoparticles applications of pharmaceutical solvates in impurity purging and final form preparation pharmaceutical cocrystal engineering to enable chiral separation the emerging technique of microcrystal electron diffraction in solid form characterization poor wettability of APIs oral delivery of peptides such as semaglutide injectable drug device combination products and N nitrosamine control in drug product This updated and revised Second Edition still features Physical and chemical properties of solid state pharmaceuticals such as amorphous forms mesophases polymorphs hydrates solvates salts co crystals nano particles and solid dispersions Characterization techniques for solid form identification and physical attribute analysis such as X Ray powder diffraction thermal analysis microscopy spectroscopy solid state NMR particle analysis water sorption mechanical property testing solubility and dissolution Applications of pharmaceutical chemistry and physical characterization techniques in developing and testing drug substances and drug products for small molecules and biopharmaceuticals This book is an essential resource on the subject for formulation scientists process chemists medicinal chemists and analytical chemists The book will also appeal to quality control quality assurance and regulatory affair specialists and advanced undergraduate and graduate students in pharmaceutical chemistry drug delivery material science crystal engineering pharmaceutics and biopharmaceutics *Developing Solid Oral Dosage Forms* Yihong Qiu,Yisheng Chen,Geoff G.Z. Zhang,Lirong Liu,William Porter,2009-03-10 Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms It covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as various aspects of state of the art techniques and approaches in pharmaceutical sciences and technologies along with examples and or case studies in product

development The objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development The specific goals are to provide readers with Basics of modern theories of physical pharmacy biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation formulation process design characterization and scale up in pharmaceutical sciences and technologies New developments challenges trends opportunities intellectual property issues and regulations in solid product development The first book ever that provides comprehensive and in depth coverage of what s required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market including the most updated science and technologies practice applications regulation intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well established authors co authors of diverse background knowledge skills and experience from industry academia and regulatory agencies *Solid State Development and Processing of Pharmaceutical Molecules* Michael Gruss,2021-11-16 Solid State Development and Processing of Pharmaceutical Molecules A guide to the lastest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain The authors noted experts on the topic examine the importance of the solid state form of chemical and biological drugs and review the development production quality control formulation and stability of medicines The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality It also includes information on relevant regulatory and intellectual property considerations This resource is aimed at professionals in the pharmaceutical industry and offers an in depth examination of the commercially relevant issues facing developers producers and distributors of drug substances This important book Provides a guide for the effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation process control and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists pharmaceutical industry professionals pharma engineers solid state chemists chemical engineers Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production Water-Insoluble Drug Formulation Ron Liu,2008-01-18 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 Solid State Characterization of Pharmaceuticals Richard A. Storey,Ingvar Ymén,2011-03-31 The field of solid state characterization is central to the pharmaceutical industry as drug products are in an overwhelming number of cases produced as solid materials Selection of the optimum solid form is a critical aspect of the development of pharmaceutical compounds due to their ability to exist in more than one form or crystal structure polymorphism These polymorphs exhibit different physical properties which can affect their biopharmaceutical properties This book provides an up to date review of the current techniques used to characterize pharmaceutical solids Ensuring balanced practical coverage with industrial relevance it covers a range of key applications in the field The following topics are included Physical properties and processes Thermodynamics Intellectual guidance X ray diffraction Spectroscopy Microscopy Particle sizing Mechanical properties Vapour sorption Thermal analysis Calorimetry Polymorph prediction Form selection Solid-State Properties of Pharmaceutical Materials Stephen R. Byrn,George Zografi,Xiaoming (Sean) Chen,2017-07-12 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 **Handbook of Stability Testing in Pharmaceutical Development** Kim Huynh-Ba,2008-11-16 This handbook is the first to cover all aspects of stability testing in pharmaceutical development

Written by a group of international experts the book presents a scientific understanding of regulations and balances methodologies and best practices **Solid-State Properties of Pharmaceutical Materials** Stephen R. Byrn,George Zografi,Xiaoming (Sean) Chen,2017-07-17 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

Pharmaceutical Crystals Tong Li,Alessandra Mattei,2018-10-16 An important resource that puts the focus on understanding and handling of organic crystals in drug development Since a majority of pharmaceutical solid state materials are organic crystals their handling and processing are critical aspects of drug development Pharmaceutical Crystals Science and Engineering offers an introduction to and thorough coverage of organic crystals and explores the essential role they play in drug development and manufacturing Written contributions from leading researchers and practitioners in the field this vital resource provides the fundamental knowledge and explains the connection between pharmaceutically relevant properties and the structure of a crystal Comprehensive in scope the text covers a range of topics including crystallization molecular interactions polymorphism analytical methods processing and chemical stability The authors clearly show how to find solutions for pharmaceutical form selection and crystallization processes Designed to be an accessible guide this book represents a valuable resource for improving the drug development process of small drug molecules This important text Includes the most important aspects of solid state organic chemistry and its role in drug development Offers solutions for pharmaceutical form selection and crystallization processes Contains a balance between the scientific fundamental and pharmaceutical applications Presents coverage of crystallography molecular interactions polymorphism analytical methods processing and chemical stability Written for both practicing pharmaceutical scientists engineers and senior undergraduate and graduate students studying pharmaceutical solid state materials Pharmaceutical Crystals Science and Engineering is a reference and textbook for understanding producing analyzing and designing organic crystals which is an imperative skill to master for anyone working in the field *Disordered Pharmaceutical Materials* Marc Descamps,2016-08-08 A one stop resource for researchers developers and post graduate students in pharmaceutical science This handbook and ready reference provides detailed but not overloaded information presenting the topic without unnecessarily complex formalism As

such it gives a systematic and coherent overview of disordered materials for pharmaceutical applications covering fundamental aspects as well as preparation and characterization techniques for the target oriented development of drug delivery systems based on disordered crystals and amorphous solids Special attention is paid to examine the different facets and levels of disorder in their structural and dynamic aspects as well as the effect of disorder on dissolution and stability Chapters on processing induced disorder and on patenting issues round off the book As a result the book helps overcoming the challenges of using these materials in the pharmaceutical industry For pharmaceutical and medicinal chemists materials scientists clinical physicists and pharmaceutical laboratories looking to make better and more potent pharmaceuticals

Polymorphism in the Pharmaceutical Industry Rolf Hilfiker,Markus von Raumer,2019-04-29 Polymorphism in the Pharmaceutical Industry Solid Form and Drug Development highlights the relevance of polymorphism in modern pharmaceutical chemistry with a focus on quality by design QbD concepts It covers all important issues by way of case studies ranging from properties and crystallization via thermodynamics analytics and theoretical modelling right up to patent issues As such the book underscores the importance of solid state chemistry within chemical and pharmaceutical development It emphasizes why solid state issues are important the approaches needed to avoid problems and the opportunities offered by solid state properties The authors include true polymorphs as well as solvates and hydrates while providing information on physicochemical properties crystallization thermodynamics quantum mechanical modelling and up scaling Important analytical tools to characterize solid state forms and to quantify mixtures are summarized and case studies on solid state development processes in industry are also provided Written by acknowledged experts in the field this is a high quality reference for researchers project managers and quality assurance managers in pharmaceutical agrochemical and fine chemical companies as well as for academics and newcomers to organic solid state chemistry **Solubility in Pharmaceutical Chemistry** Christoph Saal,Anita Nair,2020-01-20 This book describes the physicochemical fundamentals and biomedical principles of drug solubility Methods to study and predict solubility in silico and in vitro are described and the role of solubility in a medicinal chemistry and pharmaceutical industry context are discussed Approaches to modify and control solubility of a drug during the manufacturing process and of the pharmaceutical product are essential practical aspects of this book Pharmaceutical Preformulation and Formulation Mark Gibson,2016-04-19 Pharmaceutical Preformulation and Formulation A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process as well as the shift from developing small molecules to the growth of biopharmaceuticals The book meets the ne **Studies in Natural Products Chemistry** Atta-ur Rahman,2023-09-13 Studies in Natural Products Chemistry Volume 78 covers the synthesis or testing and recording of the medicinal properties of natural products providing cutting edge accounts of the fascinating developments in the isolation structure elucidation synthesis biosynthesis and pharmacology of a diverse array of bioactive

natural products Natural products in the plant and animal kingdom offer a huge diversity of chemical structures that are the result of biosynthetic processes that have been modulated over the millennia through genetic effects With rapid developments in spectroscopic techniques and accompanying advances in high throughput screening techniques it has become possible to isolate and then determine the structures and biological activity of natural products rapidly thus opening up exciting opportunities in the field of new drug development to the pharmaceutical industry Focuses on the chemistry of bioactive natural products Contains contributions by leading authorities in the field Presents sources of new pharmacophores

Pharmaceutical Stress Testing Steven W. Baertschi,Karen M. Alsante,Robert A. Reed,2016-04-19 The second edition of Pharmaceutical Stress Testing Predicting Drug Degradation provides a practical and scientific guide to designing executing and interpreting stress testing studies for drug substance and drug product This is the only guide available to tackle this subject in depth The Second Edition expands coverage from chemical stability **Green Sustainable Process for Chemical and Environmental Engineering and Science** Rajender Boddula,Mohd Imran Ahamed,Abdullah M. Asiri,2020-11-20 Green Sustainable Process for Chemical and Environmental Engineering and Science Green Solvents for Biocatalysis delivers an in depth overview of biocatalysis in green solvents for industrial applications also including outlines of sustainable methodologies in the area of organic chemistry agriculture analytical chemistry and engineering and pharmaceutical sciences The book provides unique content in the area making it a great source for information for undergraduate postgraduate students faculty R D professionals production chemists environmental engineers and industrial experts Provides a broad overview of biocatalysis of sustainable processes Discusses the use of green alternative solvents in biocatalysis Outlines eco friendly organic synthesis and chemical processes using biocatalysis Includes tactics on industrial product development using biocatalysis **Organic Chemistry of Drug Degradation** Min Li,2015-10-20 The vast majority of drugs are organic molecular entities A clear understanding of the organic chemistry of drug degradation is essential to maintaining the stability efficacy and safety of a drug product throughout its shelf life During analytical method development stability testing and pharmaceutical manufacturing troubleshooting activities one of the frequently occurring and usually challenging events would be the identification of drug degradants and understanding of drug degradation mechanisms and pathways This book is written by a veteran of the pharmaceutical industry who has first hand experience in drug design and development drug degradation mechanism studies analytical development and manufacturing process troubleshooting and improvement The author discusses various degradation pathways with an emphasis on the mechanisms of the underlying organic chemistry which should aid greatly in the efforts of degradant identification formulation development analytical development and manufacturing process improvement Organic reactions that are significant in drug degradation will first be reviewed and then illustrated by examples of drug degradation reported in the literature The author brings the book to a close with a final chapter dedicated to the strategy for rapid elucidation of drug degradants with regard to the current

regulatory requirements and guidelines One chapter that should be given special attention is Chapter 3 Oxidative Degradation Oxidative degradation is one of the most common degradation pathways but perhaps the most complex one This chapter employs more than sixty drug degradation case studies with in depth discussion in regard to their unique degradation pathways With the increasing regulatory requirements on the quality and safety of pharmaceutical products in particular with regard to drug impurities and degradants the book will be an invaluable resource for pharmaceutical and analytical scientists who engage in formulation development analytical development stability studies degradant identification and support of manufacturing process improvement In addition it will also be helpful to scientists engaged in drug discovery and development as well as in drug metabolism studies **Process Chemistry in the Pharmaceutical Industry** Kumar Gadamasetti,1999-05-06 Providing guidance for chemists and other scientists entering pharmaceutical discovery and development this up to the minute reference presents contributions from an international group of nearly 50 renowned researchers offering a solid grounding in synthetic and physical organic chemistry and clarifying the roles of various special

Decoding **Solid State Chemistry Of Drugs**: Revealing the Captivating Potential of Verbal Expression

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