



Solid-State Chemistry of Drugs

Stephen R. Byrn



Solid State Chemistry Of Drugs

JR Anderson



Solid State Chemistry Of Drugs:

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

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 is 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 Materials in Pharmaceutical Chemistry Stephen R. Byrn, George Zografi, Xiaoming (Sean) Chen, 2025-10-28. 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

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 Development and Processing of Pharmaceutical Molecules Michael Gruss, 2021-11-16 Solid State Development and Processing of Pharmaceutical Molecules 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

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 *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 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 **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 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 Characterization of Pharmaceuticals* Angeline

Zakrzewski, Marek Zakrzewski, 2006 *Handbook of Isolation and Characterization of Impurities in Pharmaceuticals*

Satinder Ahuja, Karen Mills Alsante, 2003-06-26 The United States Food and Drug Administration FDA and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation ICH be isolated and characterized Identifying process related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms When this process is performed at an early stage there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high quality drug product This book therefore has been designed to meet the need for a reference text on the complex process of isolation and characterization of process related synthesis and formulation impurities and degradation products to

meet critical regulatory requirements Its objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates drug substances and drug products The book outlines impurity identification processes and will be a key resource document for impurity analysis isolation synthesis and characterization Provides valuable information on isolation and characterization of impurities Gives a regulatory perspective on the subject Describes various considerations involved in meeting regulatory requirements Discusses various sources of impurities and degradation products

Polymorphism in Pharmaceutical Solids Harry G. Brittain, 2018-11-12 Using clear and practical examples Polymorphism of Pharmaceutical Solids Second Edition presents a comprehensive examination of polymorphic behavior in pharmaceutical development that is ideal for pharmaceutical development scientists and graduate students in pharmaceutical science This edition focuses on pharmaceutical aspects of polymorphism a *Practical Pharmaceutical Chemistry* A. H. Beckett, J. B. Stenlake, 1988-01-01 This Fourth Edition has been thoroughly revised and updated to take account of international developments in pharmaceutical chemistry and to maintain the position of Practical Pharmaceutical Chemistry as the leading University textbook in the field of pharmaceutical analysis and quality control Part 2 deals with physical techniques of analysis for more advanced courses It gives a broad coverage of the most widely used techniques in quantitative chromatography The treatment of spectroscopy and radiopharmaceuticals has also been increased There are additional chapters on the contribution and role of physical methods of analysis in the various stages of drug development and a series of workshop style exercises illustrating the application of spectroscopic techniques in structural elucidation and verification of identity Users of the two volumes will welcome the internationalisation of the text with examples based on drugs and dosage forms that are widespread and in common use in human medicine in Britain continental Europe and North America Additionally there is some reference to veterinary pharmaceuticals where they provide appropriate examples

Discovering and Developing Molecules with Optimal Drug-Like Properties Allen C Templeton, Stephen R. Byrn, Roy J Haskell, Thomas E. Prisinzano, 2014-10-31 This authoritative volume provides a contemporary view on the latest research in molecules with optimal drug like properties It is a valuable source to access current best practices as well as new research techniques and strategies Written by leading scientists in their fields the text consists of fourteen chapters with an underlying theme of early collaborative opportunities between pharmaceutical and discovery sciences The book explores the practical realities of performing physical pharmaceutical and biopharmaceutical research in the context of drug discovery with short timelines and low compound availability Chapters cover strategies and tactics to enable discovery as well as predictive approaches to establish understand and communicate risks in early development It also examines the detection characterization and assessment of risks on the solid state properties of advanced discovery and early development candidates highlighting the link between solid state properties and critical development parameters such as solubility and stability Final chapters center on techniques to improve molecular solubilization and prevent precipitation with particularly

emphasis on linking physiochemical properties of molecules to formulation selection in preclinical and clinical settings

Photostability Of Drugs And Drug Formulations Hanne Hjorth Tonnesen,1996-09-03 This text discusses various aspects of the combination of drugs and light Degradation processes stabilization of photolabile drug substances within formulations benefits from the combination of drugs and light and testing of drug photoreactivity are some of the topics discussed

Pharmaceutical Crystals Tong Li,Alessandra Mattei,2018-08-31 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 *Library of Congress Subject Headings* Library of Congress,Library of Congress.

Office for Subject Cataloging Policy,2012 **Library of Congress Subject Headings** Library of Congress. Cataloging Policy and Support Office,2009 *Preclinical Development Handbook* Shayne Cox Gad,2008-03-21 A clear straightforward resource to guide you through preclinical drug development Following this book s step by step guidance you can successfully initiate and complete critical phases of preclinical drug development The book serves as a basic comprehensive reference to prioritizing and optimizing leads dose formulation ADME pharmacokinetics modeling and regulations This authoritative easy to use resource covers all the issues that need to be considered and provides detailed instructions for current methods and techniques Each chapter is written by one or more leading experts in the field These authors representing the many disciplines involved in preclinical toxicology screening and testing give you the tools needed to apply an effective multidisciplinary approach The editor has carefully reviewed all the chapters to ensure that each one is thorough accurate

and clear Among the key topics covered are Modeling and informatics in drug design Bioanalytical chemistry Absorption of drugs after oral administration Transporter interactions in the ADME pathway of drugs Metabolism kinetics Mechanisms and consequences of drug drug interactions Each chapter offers a full exploration of problems that may be encountered and their solutions The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage This publication should be readily accessible to all pharmaceutical scientists involved in preclinical testing enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin

The Enigmatic Realm of **Solid State Chemistry Of Drugs**: Unleashing the Language is Inner Magic

In a fast-paced digital era where connections and knowledge intertwine, the enigmatic realm of language reveals its inherent magic. Its capacity to stir emotions, ignite contemplation, and catalyze profound transformations is nothing short of extraordinary. Within the captivating pages of **Solid State Chemistry Of Drugs** a literary masterpiece penned with a renowned author, readers embark on a transformative journey, unlocking the secrets and untapped potential embedded within each word. In this evaluation, we shall explore the book's core themes, assess its distinct writing style, and delve into its lasting affect the hearts and minds of those that partake in its reading experience.

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