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# Solid-State Chemistry of Drugs

Stephen R. Byrn



# Solid State Chemistry Of Drugs

**Allen C Templeton, Stephen R.  
Byrn, Roy J Haskell, Thomas E.  
Prisinzano**



## **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 Zografis, 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

**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

**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 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, and 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

**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

**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

*Solid State Characterization of Pharmaceuticals* Angeline Zakrzewski, Marek Zakrzewski, 2006

*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

**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

[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

**Stereochemical Aspects of Drug Action and Disposition** Michel F. Eichelbaum, Bernard Testa, Andrew

Somogyi, 2012-12-06 This book aims to guide and inspire drug researchers as they enter the 21st century Stereochemistry is an essential dimension in pharmacology and should be understood as such by all drug researchers whatever their background When used as probes or medicines stereoisomeric drugs offer invaluable insights or innovative therapeutic strategies The book spans the subject from the molecular to the clinical The first section on chemical aspects contains chapters on chemical synthesis analysis natural products chiral stability racemization and physical properties The second section is on experimental pharmacology with chapters on drug receptor interactions chiral recognition ion channels and molecular toxicology The third section focuses on drug disposition with chapters on absorption distribution protein binding metabolism and elimination The final section is dedicated to regulatory and clinical aspects 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 *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 **Handbook of Modern**



**Pharmaceutical Analysis** Satinder Ahuja, Stephen Scypinski, 2010-11-11 Handbook of Modern Pharmaceutical Analysis Second Edition synthesizes the complex research and recent changes in the field while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it. Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations. Features detailed coverage of QA, ethics, and regulatory guidance, quality by design, good manufacturing practice, as well as high-tech methodologies and technologies from lab on a chip to LC-MS, LC-NMR, and LC-NMR-MS.

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.

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