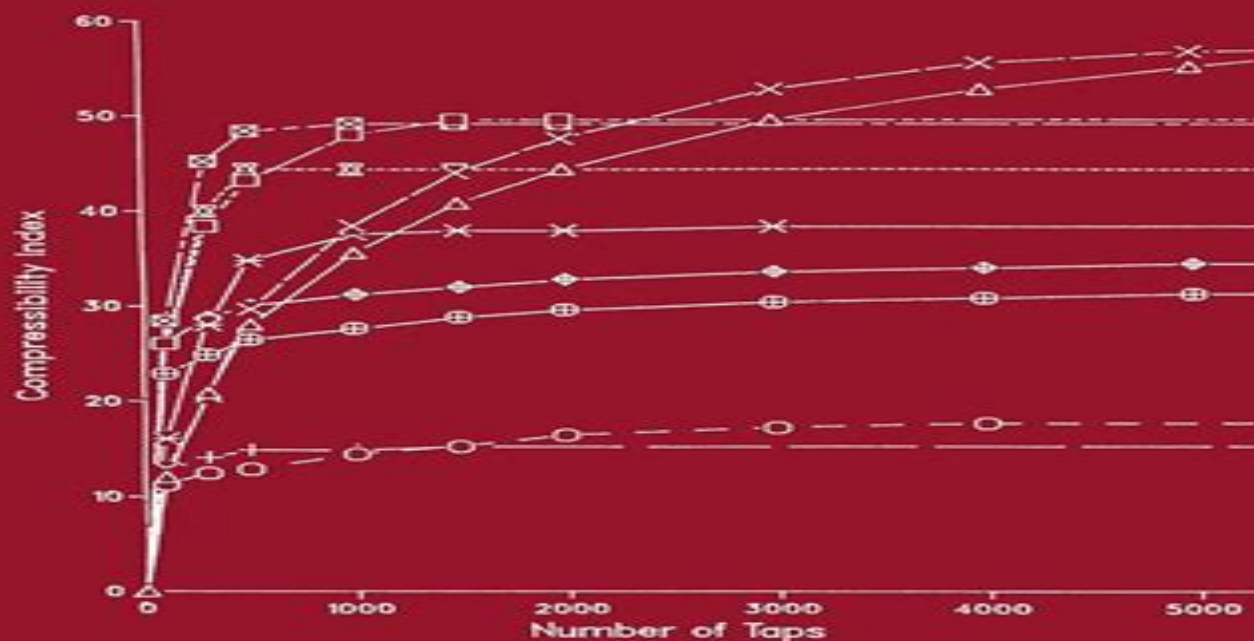


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Physical Characterization Of Pharmaceutical Solids

Kenneth W. Busch, Marianna A. Busch



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Properties of Pharmaceutical Materials Stephen R. Byrn, George Zograf, 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 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

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.

Chirality in Drug Design and Development Indra K. Reddy, Reza Mehvar, 2004-03-15
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.

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

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 **Preformulation in Solid Dosage Form Development** Moji Christianah Adeyeye, Harry G. Brittain, 2008-01-07 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 imp 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

Analytical Profiles of Drug Substances and Excipients, 1999-10-14 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

Use of High-intensity X-radiation in Solid-state Characterization of Pharmaceuticals Cletus Nunes, 2005

Characterization of Polymorphism in Crystalline Organic Compounds Using Solid-state NMR Spectroscopy Brian Edward Padden, 2000

Profiles of Drug Substances, Excipients and Related Methodology Harry G. Brittain, 2014-05-01 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 Contributions from leading authorities Informs and updates on all the latest developments in the field

Proceedings of Biomedical Applications of Raman Spectroscopy Michael D. Morris, 1999

Profiles of Drug Substances, Excipients, and Related Methodology Harry G. Brittain, 2018-04-17 Profiles of Drug Substances Excipients and Related Methodology Volume 43 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 and database compilations that fall within a variety of categories with this release focusing on Ganciclovir Mirtazapine Tolfenamic Acid Mid Infrared Spectroscopy of Pharmaceutical Solids and the Validation of Chromatographic Methods of Analysis Application for drugs that

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