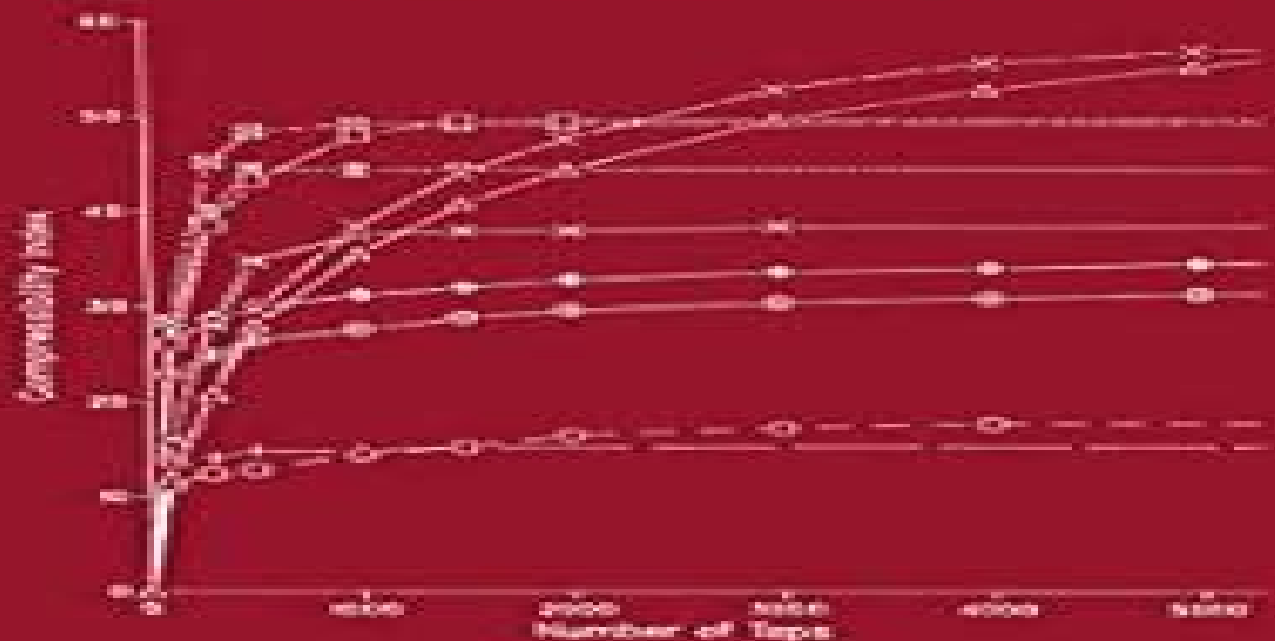


Physical Characterization of Pharmaceutical Solids



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Physical Characterization Of Pharmaceutical Solids

**Stephen R. Byrn, George
Zografi, Xiaoming (Sean) Chen**



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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

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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

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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

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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

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

Particulate Interactions in Dry Powder Formulation for Inhalation Xian Ming Zeng,Gary Peter Martin,Christopher Marriott,2000-10-26 Interactions between drug particulates are crucial in determining drug dispersion and deaggregation and ultimately delivery efficiency This book combines principles established in surface and colloidal chemistry with pharmaceutical powder technology It discusses some of the factors affecting particulate interactions and particle fluid interaction in the respiratory tract It review some of the studies carried out in dry powder formulation development and proposes possible strategies in improving DPI efficiency The majority of these principles are applicable to other pharmaceutical solid dosage forms e g tablets and capsules

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

Thermal Analysis of Pharmaceuticals Duncan Q.M. Craig, Mike Reading, 2006-12-21 As a result of the Process Analytical Technologies PAT initiative launched by the U S Food and Drug Administration FDA analytical development is receiving more attention within the pharmaceutical industry Illustrating the importance of analytical methodologies Thermal Analysis of Pharmaceuticals presents reliable and versatile charac

Theory and Practice of Contemporary Pharmaceutics Tapash K. Ghosh, Bhaskara R. Jasti, 2021-02-25 With a shift toward problem based learning and critical thinking in many health science fields professional pharmacy training faces a shift in focus as well Although the Accreditation Council for Pharmacy Education ACPE has recently suggested guidelines for problem solving to be better integrated into pharmacy curriculum pharmacy books currently available either address this material inadequately or lack it completely Theory and Practice of Contemporary Pharmaceutics addresses this problem by challenging pharmacy students to think critically in preparation for situations that arise in clinical practice This book offers a wealth of up to date information organized in a logical sequence corresponding to the art and science required for formulators in industry and dispensing pharmacists in the community It breaks down the subject to its simplest form and includes numerous examples case studies and problems In addition to presenting basic scientific principles each chapter includes a self evaluation tutorial designed to

help you evaluate your understanding of the subject matter numerical problems that provide practice in finding mathematical solutions and case studies that measure your overall grasp of the subject matter by challenging you to craft a plausible solution to a real life scenario using the concepts presented in that chapter Written by authors selected from academia industry and regulatory agencies the book presents an objective and balanced view of pharmaceutical science and its application The authors insights are extremely helpful to pharmacy students as well as practicing pharmacists involved in the development and or dispensation of existing and new generation biotechnology based drug products This simplified and user friendly book will present pharmaceutics in a way that it has never been presented before and will help prepare students and pharmacists for the competitive and challenging nature of the professional market *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 **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 **Pharmaceutical Process Validation** Robert A. Nash, Alfred H. Wachter, 2003-03-27 The third edition of this text contains additional chapters which cover troubleshooting procedures validation in contract manufacturing and current harmonization trends Industrial Applications of X-Ray Diffraction Frank Smith, 1999-09-22 By illustrating a wide range of specific applications in all major industries this work broadens the coverage of X ray diffraction

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