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P. Heinrich Stahl, Camille G. Wermuth (Eds.)

Handbook of Pharmaceutical Salts

Properties, Selection, and Use



WILEY-VCH

Handbook Of Pharmaceutical Salts Properties Selection And Use

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



Handbook Of Pharmaceutical Salts Properties Selection And Use:

Handbook of Pharmaceutical Salts Properties, Selection, and Use P. Heinrich Stahl, 2008-08-04 This comprehensive up to date guide and information source is an instructive companion for all scientists involved in research and development of drugs and in particular of pharmaceutical dosage forms The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts Altogether the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products *Pharmaceutical Salts* P. Heinrich Stahl, Camille G. Wermuth, 2011-04-18 The first edition of this handbook was a tremendous success collating the scientific literature on this topic that had otherwise been rather limited and scattered throughout numerous journals and patents The result was a comprehensive resource that addresses the preparation selection and use of pharmaceutically active salts examining the opportunities for increased efficacy and improved drug delivery provided by the selection of an optimal salt This second revised edition is designed to meet the continued interest in both the topic and the book Altogether the contributions to this book by international team of authors from academia and pharmaceutical industry reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products They present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts taking great care to address every conceivable aspect of the preparation of pharmaceutical salts An introductory chapter presents a concise review of the various objectives in the pursuit of pharmaceutically active salts followed by the theoretical background of salt formation There then follow chapters on the practice of salt formation in an industrial R D environment as well as regulatory and patent issues Practical examples for the practitioners at the lab bench are provided before the book concludes with a comprehensive annotated compilation of the individual salt forming acids and bases with their relevant properties followed by an appendix containing tables with the acids and bases sorted alphabetically and by pKa supplemented with other useful facts and data An essential reference for students of medicinal and pharmaceutical chemistry and an indispensable handbook for R D chemists analytical chemists biologists development pharmacists regulatory and patent specialists and medicinal scientists engaged in preclinical development of drugs In addition this comprehensive and up to date guide is an instructive companion for all scientists involved in the research and development of drugs and in particular of pharmaceutical dosage forms *Pharmaceutical Dosage Forms - Tablets* Larry L. Augsburger, Stephen W. Hoag, 2008-06-03 *Pharmaceutical Dosage Forms Tablets Third Edition* is a comprehensive treatment of the design formulation manufacture and evaluation of the tablet dosage form The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients *Water-Insoluble Drug Formulation* Ron Liu, 2018-03-12 *Properties and Formulation From Theory to Real World Application* 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 the much needed reformulation of currently marketed products can be significantly affected by these challenges. More recently it was reported that the percentage increased to 90% for the candidates of new chemical entities in the discovery stage and 75% for compounds under development. In the most comprehensive resource on the topic this third 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 the detailed discussion on solubility theories, solubility prediction models, the aspects of preformulation, biopharmaceutics, pharmacokinetics, regulatory and discovery support of water insoluble drugs to various techniques used in developing delivery systems for water insoluble drugs. This book includes more than 15 water insoluble drug delivery systems or technologies illustrated with case studies and 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. The aim of this book is to provide a handy reference for pharmaceutical scientists in the handling of formulation issues related to water insoluble drugs. In addition, this book may be useful to pharmacy and chemistry undergraduate students and pharmaceutical and biopharmaceutical graduate students to enhance their knowledge in the techniques of drug solubilization and dissolution enhancement.

Pharmaceutical Salts and Co-crystals Johan Wouters, Luc Quéré, 2011. His unique book focuses on the currently hot topic of Pharmaceutical Salts and Co crystals. Combining both reports of the latest academic research and comprehensive overviews of basic principles with more applied contributions from selected experts in industry.

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.

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

Generic Drug Product Development Isadore Kanfer, Leon Shargel, 2007-11-15 The assessment of bioequivalence is an important process whereby the bioavailability of a generic drug product is compared with its brand name counterpart Generic pharmaceutical products must be approved as therapeutic equivalents to the brand name alternative in order to be interchangeable The demonstration of bioequivalence is an important comp

Practical Process Research and Development Neal G. Anderson, 2012-04-09 Designed to provide a comprehensive step by step approach to organic process research and development in the pharmaceutical fine chemical and agricultural chemical industries this book describes the steps taken following synthesis and evaluation to bring key compounds to market in a cost effective manner It describes hands on step by step approaches to solving process development problems including route reagent and solvent selection optimising catalytic reactions chiral syntheses and green chemistry Second Edition highlights Reflects the current thinking in chemical process R D for small molecules Retains similar structure and orientation to the first edition Contains

approx 85% new material Primarily new examples work up and prospective considerations for pilot plant and manufacturing scale up Some new expanded topics e g green chemistry genotoxins enzymatic processes Replaces the first edition although the first edition contains useful older examples that readers may refer to Provides insights into generating rugged practical cost effective processes for the chemical preparation of small molecules Breaks down process optimization into route reagent and solvent selection development of reaction conditions workup crystallizations and more Presents guidelines for implementing and troubleshooting processes

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

Dosage Form Design Considerations, 2018-07-28 Dosage Form Design Parameters Volume I examines the history and current state of the field within the pharmaceutical sciences presenting key developments Content includes drug development issues the scale up of formulations regulatory issues intellectual property solid state properties and polymorphism Written by experts in the field this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters Chapters delve into a particular aspect of this fundamental field covering principles methodologies and the technologies employed by pharmaceutical scientists In addition the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals cosmetics biotechnology and related industries Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates graduate students and those interested in drug dosage design

Early Drug Development Fabrizio Giordanetto, 2018-06-15 This one stop reference systematically covers key aspects in early drug development that are directly relevant to the discovery phase and are required for first in human studies Its broad scope brings together critical knowledge from many disciplines

ranging from process technology to pharmacology to intellectual property issues After introducing the overall early development workflow the critical steps of early drug development are described in a sequential and enabling order the availability of the drug substance and that of the drug product the prediction of pharmacokinetics and dynamics as well as that of drug safety The final section focuses on intellectual property aspects during early clinical development The emphasis throughout is on recent case studies to exemplify salient points resulting in an abundance of practice oriented information that is usually not available from other sources Aimed at medicinal chemists in industry as well as academia this invaluable reference enables readers to understand and navigate the challenges in developing clinical candidate molecules that can be successfully used in phase one clinical trials

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 physicochemical properties of molecules to formulation selection in preclinical and clinical settings

Absorption and Drug Development Alex Avdeef, 2012-05-22 Explains how to perform and analyze the results of the latest physicochemical methods With this book as their guide readers have access to all the current information needed to thoroughly investigate and accurately determine a compound s pharmaceutical properties and their effects on drug absorption The book emphasizes oral absorption explaining all the physicochemical methods used today to analyze drug candidates Moreover the author provides expert guidance to help readers analyze the results of their studies in order to select the most promising drug candidates This Second Edition has been thoroughly updated and revised incorporating all the latest research findings methods and resources including Descriptions and applications of new PAMPA models drawing on more than thirty papers published by the author s research group Two new chapters examining permeability and Caco 2 MDCK and permeability and the blood brain barrier Expanded information and methods to support pKa determination New examples explaining the treatment of practically insoluble test compounds Additional case studies demonstrating the use of the latest physicochemical techniques New revised and

expanded database tables throughout the book Well over 200 drawings help readers better understand difficult concepts and provide a visual guide to complex procedures In addition over 800 references serve as a gateway to the primary literature in the field facilitating further research into all the topics covered in the book This Second Edition is recommended as a reference for researchers in pharmaceutical R D as well as in agrochemical environmental and other related areas of research It is also recommended as a supplemental text for graduate courses in pharmaceutics

Pharmaceutical Industry Practices on Genotoxic Impurities Heewon Lee,2014-08-29 A great deal of confusion and uncertainty over genotoxic impurity GTI identification assessment and control exists in the pharmaceutical industry today Pharmaceutical Industry Practices on Genotoxic Impurities strives to facilitate scientific and systematic consensus on GTI management by presenting rationales strategies methods interpretati

Supramolecular Synthons in Crystal Engineering of Pharmaceutical Properties Ashwini K. Nangia,2024-10-01 This comprehensive resource skillfully consolidates crystal engineering the design of organic solids and supramolecular synthons i e structural hydrogen bond units to achieve desired pharmaceutical properties including solubility dissolution bioavailability permeability particle size tableting hydration and mechanical strength Covering 30 years of crystal engineering developments and pharmaceutical applications this book will be a single and complete resource for supramolecular and structural chemists the crystal engineering community pharmaceutical scientists and industrial researchers Key Features Covers the fundamentals of crystal engineering and supramolecular synthons Details the challenges of low solubility and low permeability facing oral drug formulations Explains how heterosynthons provide a rational approach to address and implement solutions Provides case studies from academic and industrial labs to walk the reader through the actual steps Explores developments in the scale up and manufacture of crystal forms in pharmaceutical industry

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

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

Evaluation of Drug Candidates for Preclinical Development Chao Han, Charles B. Davis, Binghe Wang, 2010-01-19 Emphasizes the integration of major areas of drug discovery and their importance in candidate evaluation It is believed that selecting the right drug candidate for development is the key to success In the last decade pharmaceutical R D departments have integrated pharmacokinetics and drug metabolism pharmaceutics and toxicology into early drug discovery to improve the assessment of potential drug compounds Now Evaluation of Drug Candidates for Preclinical Development provides a complete view and understanding of why absorption distribution metabolism excretion toxicology ADMET plays a pivotal role in drug discovery and development Encompassing the three major interrelated areas in which optimization and evaluation of drug developability is most critical pharmacokinetics and drug metabolism pharmaceutics and safety assessment this unique resource encourages integrated thinking in drug discovery The contributors to this volume Cover drug transporters cytochrome P 450 and drug drug interactions plasma protein binding stability drug formulation preclinical safety assessment toxicology and toxicokinetics Address developability issues that challenge pharma companies moving beyond isolated experimental results Reveal connections between the key scientific areas that are critical for successful drug discovery and development Inspire forward thinking strategies and decision making processes in preclinical evaluation to maximize the potential of drug candidates to progress through development efficiently and meet the increasing demands of the marketplace Evaluation of Drug Candidates for Preclinical Development serves as an introductory reference for those new to the pharmaceutical industry and drug discovery in particular It is especially well suited for scientists and management teams in small to mid sized pharmaceutical companies as well as academic researchers and graduate students

concerned with the practical aspects related to the evaluation of drug developability

Therapeutic Delivery Solutions

Chung Chow Chan, Kwok Chow, Bill McKay, Michelle Fung, 2014-06-27 Provides a comprehensive review of all types of medical therapeutic delivery solutions from traditional pharmaceutical therapy development to innovative medical device therapy treatment to the recent advances in cellular and stem cell therapy development Provides information to potentially allow future development of treatments with greater therapeutic potential and creativity Includes associated regulatory requirements for the development of these therapies Provides a comprehensive developmental overview on therapeutic delivery solutions Provides overview information for both the general reader as well as more detailed references for professionals and specialists in the field

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