

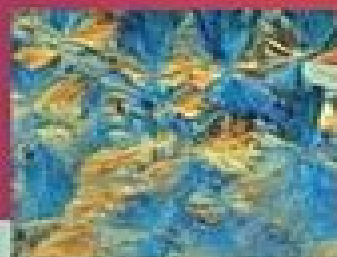
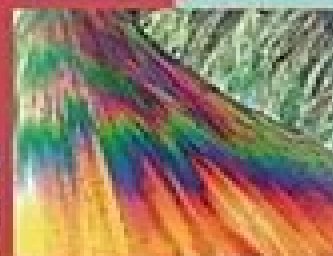
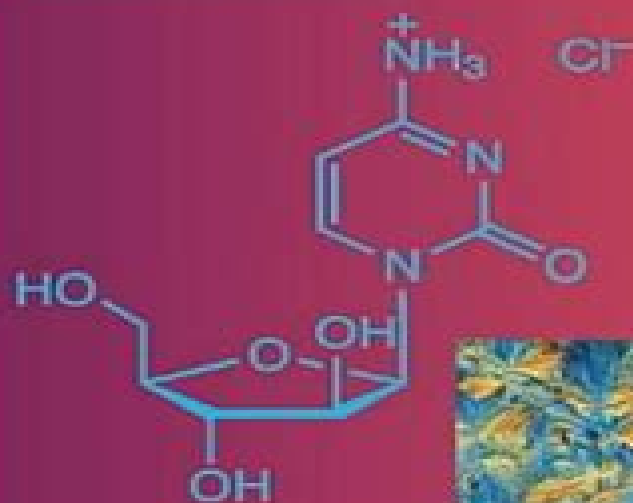


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P. Heinrich Stahl, Camille G. Wermuth (Eds.)

Handbook of Pharmaceutical Salts

Properties, Selection, and Use



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Second, Revised
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Handbook Of Pharmaceutical Salts:

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 Handbook of Pharmaceutical Analysis Lena Ohannesian, Anthony Streeter, 2001-11-09 Exploring the analysis of pharmaceuticals including polymorphic forms this book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and

decomposition products using such techniques as mass spectrometry The book provides more than 300 tables equations drawings and photographs and convenient easy to use indices facilitating quick access to each topic

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

Pharmaceutical Salts and Co-crystals Johan Wouters,Luc Quéré,2011-11-04 From crystal structure prediction to totally empirical screening the quest for new crystal forms has become one of the most challenging issues in the solid state science and particularly in the pharmaceutical world In this context multi component crystalline materials like co crystals have received renewed interest as they offer the prospect of optimized physical properties As illustrated in this first book_ entirely dedicated to this emerging class of pharmaceutical compounds_ the outcome of such endeavours into crystal engineering have demonstrated clear impacts on production marketing and intellectual property protection of active pharmaceutical ingredients APIs Indeed co crystallization influences relevant physico chemical parameters such as solubility dissolution rate chemical stability melting point hygroscopicity and often offers solids with properties superior to those of the free drug Combining both reports of the latest research and comprehensive overviews of basic principles with contributions from selected experts in both academia and industry this unique book is an essential reference ideal for pharmaceutical development scientists and graduate students in pharmaceutical science

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 Early Drug Development Fabrizio Giordanetto, 2018-06-11 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

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 **Aulton's Pharmaceutics**

E-Book Kevin M.G. Taylor, Michael E. Aulton, 2021-04-23 The essential pharmaceutics textbook One of the world's best known texts on pharmaceutics Aulton's Pharmaceutics offers a complete course in one book for students in all years of undergraduate pharmacy and pharmaceutical sciences degrees Thoroughly revised updated and extended by experts in their fields and edited by Professors Kevin Taylor and Michael Aulton this new edition includes the science of formulation pharmaceutical manufacturing and drug delivery All aspects of pharmaceutics are covered in a clear and readily accessible way and extensively illustrated throughout providing an essential companion to the entire pharmaceutics curriculum from day one until the end of the course Fully updated throughout with the addition of new chapters to reflect advances in formulation and drug delivery science pharmaceutical manufacturing and medicines regulation Designed and written for newcomers to the design and manufacture of dosage forms Relevant pharmaceutical science covered throughout Includes the science of formulation and drug delivery Reflects current practices and future applications of formulation and drug

delivery science to small drug molecules biotechnology products and nanomedicines Key points boxes throughout Over 400 online multiple choice questions *Early Drug Development* Mitchell N. Cayen, 2011-02-25 The focus of early drug development has been the submission of an Investigational New Drug application to regulatory agencies Early Drug Development Strategies and Routes to First in Human Trials guides drug development organizations in preparing and submitting an Investigational New Drug IND application By explaining the nuts and bolts of preclinical development activities and their interplay in effectively identifying successful clinical candidates the book helps pharmaceutical scientists determine what types of discovery and preclinical research studies are needed in order to support a submission to 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

Solvent Systems and Their Selection in Pharmaceutics and Biopharmaceutics Patrick Augustijns, Marcus Brewster, 2007-08-06 Solvent systems are integral to drug development and pharmaceutical technology This single topic encompasses numerous allied subjects running the gamut from recrystallization solvents to biorelevant media The goal of this contribution to the AAPS Biotechnology Pharmaceutical Aspects series is to generate both a practical handbook as well as a reference allowing the reader to make effective decisions concerning the use of solvents and solvent systems To this end the monograph was

created by inviting recognized experts from a number of fields to author relevant sections Specifically 15 chapters have been designed covering the theoretical background of solubility the effect of ionic equilibria and pH on solubilization the use of solvents to effect drug substance crystallization and polymorph selection the use of solvent systems in high throughput screening and early discovery solvent use in preformulation the use of solvents in bio relevant dissolution and permeation experiments solvents and their use as toxicology vehicles solubilizing media and excipients in oral and parenteral formulation development specialized vehicles for protein formulation and solvent systems for topical and pulmonary drug administration The chapters are organized such that useful decision trees are included together with the scientific underpinning for their application In addition trends in the use of solvent systems and a balance of current views make this monograph useful to both the novice and experienced researcher and to scientists at all developmental stages from early discovery to late pharmaceutical operations

Encyclopedia of Ionic Liquids Suojiang Zhang, 2023-02-03 The encyclopedia consists 13 subareas as follows 1 Synthesis and Characterisation of Ionic Liquids Section Editors Prof Fu Wei Li and Prof Zhen Li 2 Physicochemical Properties of Ionic Liquids Section Editors Asso Prof Qing Zhou Prof Xingmei Lu and Prof Xiaoyan Ji 3 Computational and Theoretical Modeling of Ionic Liquids Section Editors Prof Guang Feng and Prof Peter T Cummings 4 Toxicology and Biodegradation of Ionic Liquids Section Editors Prof Chunxi Li and Prof Stefan Stolte 5 Ionic Liquids in Electrochemistry Section Editors Prof Yingying Lu Prof Houlong Zhuang and Prof Chuan Zhao 6 Ionic Liquids in Organic Reaction Section Editors Prof Liang Nian He and Prof Bhalchandra M Bhanage 7 Ionic Liquids in Separation Section Editors Prof Huabin Xing 8 Ionic Liquids in Biomass and Biomolecules Section Editors Prof Toshiyuki Itoh and Prof Jian Sun 9 Ionic Liquids in Materials Science Section Editors Prof Sheng Dai and Prof Tao Wang 10 Ionic Liquids in Polymer Science Section Editors Asso Prof Jinming Zhang and Prof Jun Zhang 11 Ionic Liquids in Environmental Science Section Editors Prof Tiancheng Mu Prof Arunprakash T Karunanithi and Prof Yingxiong Wang 12 Ionic Liquids in Green Chemistry Section Editors Prof Buxing Han and Prof Peter Licence 13 Emerging Applications of Ionic Liquids Pharmacology Food Science Agriculture Nuclear Science Technology Optics Section Editors Prof Zhonghao Li and Prof Maya Guncheva This encyclopedia is systematic and comprehensive with detailed descriptions about theory technology and industrial applications This encyclopedia is valuable for students researchers and industrial players giving them a quick understanding and overview of ionic liquids in various aspects

Advanced Drug Delivery Ashim Mitra, Chi H. Lee, Kun Cheng, 2013-08-26 Provides both fundamentals and new and emerging applications Advanced Drug Delivery brings readers fully up to date with the state of the science presenting the basics formulation strategies and therapeutic applications of advanced drug delivery The book demonstrates how core concepts of pharmaceutical sciences chemistry and molecular biology can be combined and applied in order to spark novel ideas to design and develop advanced drug delivery systems for the treatment of a broad range of human diseases Advanced Drug Delivery features contributions from an international team of pharmaceutical scientists

Chapters reflect a thorough review and analysis of the literature as well as the authors firsthand experience developing drug delivery systems The book is divided into four parts Part I Introduction and Basics of Advanced Drug Delivery explores physiological barriers stability transporters and biomaterials in drug delivery Part II Strategies for Advanced Drug Delivery offers tested and proven strategies for advanced delivery of both small molecules and macromolecules Part III Translational Research of Advanced Drug Delivery focuses on regulatory considerations and translational applications of advanced drug delivery systems for the treatment of cardiovascular diseases cancer sexually transmitted diseases ophthalmic diseases and brain diseases Part IV Future Applications of Advanced Drug Delivery in Emerging Research Areas examines stem cell research cell based therapeutics tissue engineering and molecular imaging Each chapter provides objectives and assessment questions to help readers grasp key concepts and assess their knowledge as they progress through the book Advanced Drug Delivery is recommended for graduates and upper level undergraduates in the pharmaceutical sciences who need a solid foundation in the basics It is also recommended for pharmaceutical professionals who want to take advantage of new and emerging applications in advanced drug delivery systems

Medicinal Chemist's Guide to Solving ADMET Challenges

Patrick Schneider, 2021-08-20 The Medicinal Chemist's Guide to Solving ADMET Challenges summarizes a series of design strategies and tactics that have been successfully employed across pharmaceutical and academic laboratories to solve common ADMET issues These are exemplified with a curated collection of concrete examples displayed in a highly visual table of contents style format allowing readers to rapidly identify the most promising approaches applicable to their own challenges Each ADMET parameter is introduced in a concise yet comprehensive manner and includes background relevance and screening strategies Medicinal chemistry knowledge of how best to modify molecular structure to solve ADMET issues is challenging to retrieve from the literature public databases and even corporate data warehouses The Medicinal Chemist's Guide to Solving ADMET Challenges addresses this gap by presenting state of the art design strategies put together by a global group of experienced medicinal chemists and ADMET experts across academia and the pharmaceutical industry

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

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

The Role of Microstructure in Topical Drug Product Development Nigel Langley, Bozena Michniak-Kohn, David W. Osborne, 2019-08-07 Following the Semi solid Microstructure Workshop sponsored by BASF and hosted by the Rutgers Center for Dermal Research a pharmaceutical product development working group was formed The group known as the Q3 Working Group selected the following five areas of focus Particle Globule Size and Distribution Viscosity Rheology Spreadability In Vitro Testing State of API State of Excipients A committee was appointed for each of these five areas The committees were tasked to review the literature identify best practices list experimental details required for an independent lab to duplicate the test and propose scientific studies that may meaningfully advance this specific area of focus Each committee has a chair or co chairs that are the lead author s of the chapter The Q3 Working Group members serve as the critical reviewers of each chapter making suggestions that improve the quality of the document and that make each of the five chapters uniform in scope and content Pharmaceutical development scientists that formulate topical products creams lotions gels suspensions foams etc and all the allied raw material suppliers packaging suppliers contract laboratories including CROs CMOs and regulators need access to this book Overall the topic of semisolid microstructure is of equal importance to the generic pharmaceutical companies filing Abbreviated New Drug Applications or ANDAs and pharmaceutical companies filing New Drug Applications NDAs In addition to products applied to the skin hair and nails The Role of Microstructure in Topical Drug Product Development crosses over and is essential reading to developers of oral suspensions ophthalmic ointments and gels otic suspension vaginal semisolids and retention enemas

Nonclinical Drug Administration Shayne C. Gad, Charles B. Spainhour, 2017-08-14 If we will ever achieve Paul Ehrlich s magic bullet that is a molecule which goes with high selectivity to the therapeutic target site does what it needs to do and is subsequently cleared from the body the practice of safety assessment will have to change Nonclinical Drug Administration Formulations Routes and Regimens for Solving Drug Delivery Problems in Animal Model Systems seeks to address a trio of objectives that though separate are linked and central to biomedical science and ultimately medicine Rather seeing these as separate silos those working in nonclinical safety assessment will have to view these three in an integrated manner and to regularly and

thoughtfully incorporate new information and technology The trio of objectives this book explores are first to present how to deliver more of a drug product systemically to facilitate the regulatory need for evaluating safety and efficacy in animal species at elevated exposure levels prior to advancing the drug to human testing second is to achieve better tolerance to therapeutics administration in test animals and humans which achieves objectives 1 and 3 and third to explore ways to improve on therapeutic target receptor delivery performance therefore improving both clinical pharmacodynamics bioavailability and specificity The book s ten chapters assemble the basic concepts principles and hypotheses involved in quantitative receptor and chronological organism interaction dynamics central to the successful development of new therapeutics which depend on systemic administration to achieve desired therapeutic goals and in so doing avoid outcomes which limit marginalize or preclude the therapeutic use of so many molecules

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

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