

Method Development and Validation for Particle Size and Shape Measurements

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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

Determination of particle sizes in the pharmaceutical industry Karin Liltorp, Søren Lund Kristensen, Thomas Andresen, 2014-03-03 At Particle Analytical we have been working with determination of particle sizes for the pharmaceutical industry since 2000 Our customers have in general showed a large interest for an introduction to this area from a down to earth and practical perspective The intended readers of this booklet are pharmacists and technicians working with determination of particles sizes This booklet is not meant as a thorough introduction into theory behind determination of particle sizes and only a limited number of references will be given The booklet is primarily based on our own experiences and is a practical introduction to the area with a brief introduction to why and how in determination of particle sizes

International Stability Testing David J. Mazzo, 2020-08-26 In this book recognized industry experts and regulatory inspectors from the world's pharmaceutical manufacturing regions provide stability requirements in all the major markets and discuss all aspects of stability testing and biotechnology Participants in the ICH debates interpret the ICH guidelines Other discussions focus on European requirements the ICH initiatives the US SUPAC initiative matrixing and bracketing approaches from the cGMP and FDA perspective and stability requirements in Japan Australia and WHO Stress programs testing of preservatives and physical stability topics are addressed as well as various protocols and statistical approaches

Chemical Engineering in the Pharmaceutical Industry David J. am Ende, Mary T. am Ende, 2019-04-23 A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers The 2nd Edition is divided into two separate books 1 Active Pharmaceutical Ingredients API's and 2 Drug Product Design Development and

Modeling The active pharmaceutical ingredients book puts the focus on the chemistry chemical engineering and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product The drug substance operations section includes information on chemical reactions mixing distillations extractions crystallizations filtration drying and wet and dry milling In addition the book includes many applications of process modeling and modern software tools that are geared toward batch scale and continuous drug substance pharmaceutical operations This updated second edition Contains 30 new chapters or revised chapters specific to API covering topics including manufacturing quality by design computational approaches continuous manufacturing crystallization and final form process safety Expanded topics of scale up continuous processing applications of thermodynamics and thermodynamic modeling filtration and drying Presents updated and expanded example calculations Includes contributions from noted experts in the field Written for pharmaceutical engineers chemical engineers undergraduate and graduate students and professionals in the field of pharmaceutical sciences and manufacturing the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design formulation and manufacture of drug substance and products

Essential Chemistry for Formulators of Semisolid and Liquid Dosages Vitthal S. Kulkarni, Charles Shaw, 2015-10-15 A needed resource for pharmaceutical scientists and cosmetic chemists Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations The book covers foundational surface colloid chemistry which forms the necessary background for making emulsions suspensions solutions and nano drug delivery systems and the chemistry of mixing which is critical for further formulation of drug delivery systems into semisolid gels creams lotions and ointments or liquid final dosages Expanding on these foundational principles this useful guide explores stability testing methods such as particle size rheological viscosity microscopy and chemical and closes with a valuable discussion of regulatory issues Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

Integrated Pharmaceutics Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2013-02-11 Focusing on the application of physical pharmacy drug design and drug regulations as they relate to produce effective dosage forms for drug delivery Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design describing the science and art behind the concepts of dosage form development Combining physical pharmacy product design and regulatory affairs issues in a single book the authors address topics governing drug regulations of United States European and Japanese agencies and detail new regulatory guidelines

including quality by design design space analysis and blend sample uniformity Early Drug Development, 2 Volume Set
 Fabrizio Giordanetto, 2018-12-10 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 **Pharmaceutical Analysis**
 David C Lee, Michael L. Webb, 2009-02-12 The use of analytical sciences in the discovery development and manufacture of pharmaceuticals is wide ranging From the analysis of minute amounts of complex biological materials to the quality control of the final dosage form the use of analytical technology covers an immense range of techniques and disciplines This book concentrates on the analytical aspects of drug development and manufacture focusing on the analysis of the active ingredient or drug substance It provides those joining the industry or other areas of pharmaceutical research with a source of reference to a broad range of techniques and their applications allowing them to choose the most appropriate analytical technique for a particular purpose The volume is directed at analytical chemists industrial pharmacists organic chemists pharmaceutical chemists and biochemists *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

A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials National Research Council, Division on Engineering and Physical Sciences, National Materials and Manufacturing Board, Division on Earth and Life Studies, Board on Chemical Sciences and Technology, Board on Environmental Studies and Toxicology, Committee to Develop a Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials, 2012-06-09 The nanotechnology sector which generated about 225 billion in product sales in 2009 is predicted to expand rapidly over the next decade with the development of new technologies that have new capabilities The increasing production and use of engineered nanomaterials ENMs may lead to greater exposures of workers consumers and the environment and the unique scale specific and novel properties of the materials raise questions about their potential effects on human health and the environment Over the last decade government agencies academic institutions industry and others have conducted many assessments of the environmental health and safety EHS aspects of nanotechnology The results of those efforts have helped to direct research on the EHS aspects of ENMs However despite the progress in assessing research needs and despite the research that has been funded and conducted developers regulators and consumers of nanotechnology enabled products remain uncertain about the types and quantities of nanomaterials in commerce or in development their possible applications and their associated risks A Research Strategy for Environmental Health and Safety Aspects of Engineered Nanomaterials presents a strategic approach for developing the science and research infrastructure needed to address uncertainties regarding the potential EHS risks of ENMs The report summarizes the current state of the science and high priority data gaps on the potential EHS risks posed by ENMs and describes the fundamental tools and approaches needed to pursue an EHS risk research strategy The report also presents a proposed research agenda short term and long term research priorities and estimates of needed resources and concludes by focusing on implementation of the research strategy and evaluation of its progress elements that the committee considered integral to its charge

Modern Pharmaceutical Analytical Techniques Mr. Rohit Manglik, 2024-07-04 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various streams and levels

The Future of Pharmaceutical Product Development and Research, 2020-08-19 The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences also highlighting key developments research and future opportunities Written by experts in the field this volume in the Advances in

Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development Each chapter covers fundamental principles advanced methodologies and technologies employed by pharmaceutical scientists researchers and the pharmaceutical industry The book focuses on excipients radiopharmaceuticals and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice GMP guidelines Researchers and students will find this book to be a comprehensive resource for those working in and studying pharmaceuticals cosmetics biotechnology foods and related industries

HPLC and UHPLC for Practicing Scientists Michael W. Dong, 2019-07-23 A concise yet comprehensive reference guide on HPLC UHPLC that focuses on its fundamentals latest developments and best practices in the pharmaceutical and biotechnology industries Written for practitioners by an expert practitioner this new edition of HPLC and UHPLC for Practicing Scientists adds numerous updates to its coverage of high performance liquid chromatography including comprehensive information on UHPLC ultra high pressure liquid chromatography and the continuing migration of HPLC to UHPLC the modern standard platform In addition to introducing readers to HPLC s fundamentals applications and developments the book describes basic theory and terminology for the novice and reviews relevant concepts best practices and modern trends for the experienced practitioner HPLC and UHPLC for Practicing Scientists Second Edition offers three new chapters One is a standalone chapter on UHPLC covering concepts benefits practices and potential issues Another examines liquid chromatography mass spectrometry LC MS The third reviews the analysis of recombinant biologics particularly monoclonal antibodies mAbs used as therapeutics While all chapters are revised in the new edition five chapters are essentially rewritten HPLC columns instrumentation pharmaceutical analysis method development and regulatory aspects The book also includes problem and answer sections at the end of each chapter Overviews fundamentals of HPLC to UHPLC including theories columns and instruments with an abundance of tables figures and key references Features brand new chapters on UHPLC LC MS and analysis of recombinant biologics Presents updated information on the best practices in method development validation operation troubleshooting and maintaining regulatory compliance for both HPLC and UHPLC Contains major revisions to all chapters of the first edition and substantial rewrites of chapters on HPLC columns instrumentation pharmaceutical analysis method development and regulatory aspects Includes end of chapter quizzes as assessment and learning aids Offers a reference guide to graduate students and practicing scientists in pharmaceutical biotechnology and other industries Filled with intuitive explanations case studies and clear figures HPLC and UHPLC for Practicing Scientists Second Edition is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology It will be a great benefit to every busy laboratory analyst and researcher

Pharmaceutical Microscopy Robert Allen Carlton, 2011-05-04 Microscopy plays an integral role in the research and development of new medicines Pharmaceutical Microscopy describes a wide variety of techniques together with numerous practical applications of importance in drug development The first section presents

general methods and applications with an emphasis on the physical science aspects Techniques covered include optical crystallography thermal microscopy scanning electron microscopy energy dispersive x ray spectrometry microspectroscopy infrared and Raman and particle size and shape by image analysis The second section presents applications of these techniques to specific topics of pharmaceutical interest including studies of polymorphism particle size and shape analysis and contaminant identification Pharmaceutical Microscopy is designed for those scientists who must use these techniques to solve pharmaceutical problems but do not need to become expert microscopists Consequently each section has exercises designed to teach the reader how to use and apply the techniques in the book Although the focus is on pharmaceutical development workers in other fields such as food science and organic chemistry will also benefit from the discussion of techniques and the exercises Provides comprehensive coverage of key microscopy techniques used in pharmaceutical development Helps the reader to solve specific problems in pharmaceutical quality assurance Oriented and designed for pharmaceutical scientists who need to use microscopy but are not expert microscopists Includes a large number of practical exercises to give the reader hands on experience with the techniques Written by an author with 21 years of experience in the pharmaceutical industry

Guidelines for Air Sampling and Analytical Method Development and Evaluation ,1995

Handbook of Modern Pharmaceutical Analysis Satinder Ahuja,Stephen Scypinski,2001-08-02 This book describes the role modern pharmaceutical analysis plays in the development of new drugs Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug Coverage includes state of the art topics such as analytics for combinatorial chemistry and high throughput screening formulation development stability studies international regulatory aspects and documentation and future technologies that are likely to impact the field Emphasis is placed on current easy to follow methods that readers can apply in their laboratories No book has effectively replaced the very popular text Pharmaceutical Analysis that was edited in the 1960s by Tak Higuchi This book will fill that gap with an up to date treatment that is both handy and authoritative

Near-Infrared Spectroscopy Yukihiro

Ozaki,Christian Huck,Satoru Tsuchikawa,Søren Balling Engelsen,2020-11-13 This book provides knowledge of the basic theory spectral analysis methods chemometrics instrumentation and applications of near infrared NIR spectroscopy not as a handbook but rather as a sourcebook of NIR spectroscopy Thus some emphasis is placed on the description of basic knowledge that is important in learning and using NIR spectroscopy The book also deals with applications for a variety of research fields that are very useful for a wide range of readers from graduate students to scientists and engineers in both academia and industry For readers who are novices in NIR spectroscopy this book provides a good introduction and for those who already are familiar with the field it affords an excellent means of strengthening their knowledge about NIR spectroscopy and keeping abreast of recent developments

Particle Size Measurements Henk G. Merkus,2009-01-07

This book focuses on the practical aspects of particle size measurement a major difference with existing books which have a

more theoretical approach Of course the emphasis still lies on the measurement techniques For optimum application their theoretical background is accompanied by quantitative quality aspects limitations and problem identification In addition the book covers the phenomena of sampling and dispersion of powders either of which may be dominant in the overall analysis error Moreover there are chapters on the general aspects of quality for particle size analysis quality management reference materials and written standards in and on line measurement definitions and multilingual terminology and on the statistics required for adequate interpretation of results Importantly a relation is made to product performance both during processing as well as in final application In view of its set up this book is well suited to support particle size measurement courses

Translational Medicine Robert A. Meyers, 2018-07-16 Dieses Referenzwerk bietet einen vollständigen Überblick über die verschiedenen Phasen der Wirkstoffentwicklung und greift dabei auf einen translationalen Ansatz zurück

Controlled Pulmonary Drug Delivery Hugh D.C. Smyth, Anthony J. Hickey, 2011-06-24 The pace of new research and level of innovation repeatedly introduced into the field of drug delivery to the lung is surprising given its state of maturity since the introduction of the pressurized metered dose inhaler over a half a century ago It is clear that our understanding of pulmonary drug delivery has now evolved to the point that inhalation aerosols can be controlled both spatially and temporally to optimize their biological effects These abilities include controlling lung deposition by adopting formulation strategies or device technologies and controlling drug uptake and release through sophisticated particle technologies The large number of contributions to the scientific literature and variety of excellent texts published in recent years is evidence for the continued interest in pulmonary drug delivery research This reference text endeavors to bring together the fundamental theory and practice of controlled drug delivery to the airways that is unavailable elsewhere Collating and synthesizing the material in this rapidly evolving field presented a challenge and ultimately a sense of achievement that is hopefully reflected in the content of the volume

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