Granulation Preparation Evaluation Control

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Granulation Preparation Evaluation Control *2022-03-27*

KENDRICK ASHER

Pesticide Formulations and Application Systems CRC Press
WHAT HAPPENED IN KANAZAWA? THE BIRTH OF eCAM This book contains the proceedings of the International Symposium on Complementary and Alternative Medicine, (CAM) which was convened in Kanazawa Japan, November 8-10, 2002. The participants were mainly from Japan, USA, China, France, England, Germany, Taiwan, and India. The world of western medicine is gradually opening its doors to new ways of ap proaching healing. Since many of these approaches began centuries and even millennia ago in Asia, it was entirely appropriate to open our symposium in Kanazawa, a beautiful, traditional city located on the Sea of Japan. Experts from Asia, Europe and the United States gathered together for true discussions on complementary and alternative medicine and its role developing all over the world. As scientists, we listened to historical perspec tives from India, China and Japan, where CAM is still being practiced as it has been for centuries. It is well to mention at the outset that this book will cover a rapidly growing field that has strong advocates but others who are less than enthusiastic. This should be evident by the presentation of chapters that aim to significantly dispel some of the criticisms of pseudoscience and myth that often surround the discipline. It is our purpose to present high quality peer reviewed chapters.
From Conception to Post-Approval Elsevier
There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.
How to Develop Robust Solid Oral Dosage Forms CRC Press
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
Handbook of Pharmaceutical Wet Granulation Academic Press
How to Develop Robust Solid Oral Dosage Forms from Conception to Post-Approval uses a practical and hands-on approach to cover the development process of solid oral dosage forms in one single source. The book details all of the necessary steps from formulation through the post-approval phase and contains industry case studies, real world advice, and troubleshooting tips. By merging the latest scientific information with practical instructions, this book provides pharmaceutical scientists in formulation research and development with a concrete look at the key aspects in the development of solid oral dosage forms. Focuses on important topics, such as robustness, bioavailability, formulation design, continuous processing, stability tests, modified release dosage forms, international guidelines, process scale-up, and much more Part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin Discusses common, real-world problems and offers both theoretical and practical solutions to these everyday issues
A Guide to Regulatory Success, Second Edition ASTM International
There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.
Chemical Engineering in the Pharmaceutical Industry CRC Press
Handbook of Pharmaceutical Wet Granulation: Theory and Practice in a Quality by Design Paradigm offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation, taking a holistic approach by combining introductory principles with practical solutions. Chapters are written by international experts across industry, academic and regulatory settings, and cover a wide spectrum of relevant and contemporary wet granulation topics, techniques and processes. The books' focus on process analytical technology, quality by design principles, granulation equipment, modeling, scale-up, control and real time release makes it a timely and valuable resource for all those involved in pharmaceutical wet granulation. Discusses fundamentals of theory and current industrial practice in the field of wet granulation, including product and process design and role of material properties in wet granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies (PATs), and product development and scale-up paradigms Written for scientists working within the pharmaceutical industry, as well as academics, regulatory officials and equipment vendors who provide PAT tools and granulation equipment
Handbook of Pharmaceutical Granulation Technology Springer Science & Business Media
This book gathers technical and scientific articles by leading experts from 15 countries and originally presented at the world’s most prestigious forum on coal preparation: the XVIII International Coal Preparation Congress. Topics addressed include: the mineral resources basis of the coal industry; problems and prospects of development in the coal industry; crushing, grinding, screening and classification processes used at sorting plants; coal processing and briquette factories; review of plant designs and operations used around the world; new developments in dense-medium separators, water-based separation processes, froth flotation and dewatering; technologies and equipment for the dry separation of coal; coal deep processing technologies and equipment; energy generation as an area of coal deep processing; and simulation and optimization software for separation processes.In general, the future of coal around the world is defined by its competitiveness. As the cheapest form of fuel (comparatively speaking), coal undoubtedly continues to be in high demand around the world.
Pharmaceutical Theory and Practice ScholarlyEditions
In recent years, emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of excipients and in-depth understanding of their roles in drug delivery applications. This book presents a concise summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications. Each chapter is contributed by chosen experts in their respective fields, which affords truly in-depth perspective into a spectrum of excipient-focused topics. This book captures current subjects of interest – with the most up to date research updates – in the field of pharmaceutical excipients. This includes areas of interest to the biopharmaceutical industry users, students, educators, excipient manufacturers, and regulatory bodies alike.
Estimation and Control of Two-component Granulation Processes Springer Science & Business Media
Handbook of Pharmaceutical Wet GranulationTheory and Practice in a Quality by Design ParadigmAcademic Press
Pharmaceutical Dosage Forms - Tablets CRC Press
This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration, process control, process modelling, scale-up, emerging particle engineering technologies, along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe. Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology. Every pharmaceutical scientist should own a copy of this fourth edition resource. Key Features: Theoretical discussions covering granulation and engineering perspectives. Covers new advances in expert systems, process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies
Federal Register John Wiley & Sons
Controlled Release in Oral Drug Delivery provides focus on specific topics, complementing other books in the initial CRS series. Each chapter sets the context for the inventions described and describe the latitude that the inventions allow. In order to provide some similar look to each chapter, the coverage includes the historical overview, candidate drugs, factors influencing design and development, formulation and manufacturing and delivery system design. This volume was written along three main sections: the relevant anatomy and physiology, a discussion on candidates for oral drug delivery and the major three groups of controlled release systems: diffusion control (swelling and inert matrices); environmental control (pH sensitive coatings, time control, enzymatic control, pressure control) and finally lipidic systems.
Water-Insoluble Drug Formulation Springer Science & Business Media
PLATELETS is the definitive current source of state-of-the-art knowledge about platelets and covers the entire field of platelet biology, pathophysiology, and clinical medicine. Recently there has been a rapid expansion of knowledge in both basic biology and the clinical approach to platelet-related diseases including thrombosis and hemorrhage. Novel platelet function tests, drugs, blood bank storage methods, and gene therapies have been incorporated into patient care or are in development. This book draws all this information into a single, comprehensive and authoritative resource. · First edition won Best Book in Medical Science Award from the Association of American Publishers · Contains fourteen new chapters on topics such as platelet genomics and proteomics, inhibition of platelet function by the endothelium, clinical tests of platelet function, real time in vivo

imaging of platelets, and inherited thrombocytopenias · A comprehensive full color reference comprising over 70 chapters, 1400 pages, and 16,000 references

Cumulated Index Medicus John Wiley & Sons

There are many systems in different fields which consist of particle populations such as crystallization, polymerization, granulations and viral infections. The particles in these systems are characterized by their properties e.g. type, size and/or composition. Mostly, the governing equation for these dispersed systems includes a population balance resulting in an equation that involves both integrals and derivatives of an unknown function called integro-differential equation. In general, there is no analytical solution for these types of dynamic systems. This paper studies one of this particulate processes has been enhanced for application in the pharmaceutical industry; two-component high shear granulation. In this process, the granules are stuck together and form bigger particles through use of inactive binder droplets called excipient. In an ideal granulation process the composition and size of produced granules is the same, however, in reality the particle size and composition are distributed over a range.We address the issue of state estimation and control of a stochastic particulate process through (i) using model reduction to obtain a tractable approximation of the governing dynamics, (ii) designing a fast moving-horizon estimator for the reduced-order model and (iii) developing a Stochastic Model Predictive Control (SMPC) for the system. We first use the method of moments to reduce the governing integro-differential equation down to a nonlinear ordinary differential equation (ODE). In order to simplify the results of the method of moments, we exploit Taylor expansion and derive a closed finite-dimensional ordinary differential equation set. However, this approach cannot be used for composition-dependent models. To address this issue, this dissertation proposes a new model reduction approach using the method of moments in conjunction with Laguerre polynomials. In this way, we expand the distribution function over the set of orthogonal Laguerre polynomials which are function of moments. Also, we evaluate our new reduced models with the results obtained from a Monte Carlo simulation as a bench mark. These models will be the foundation for efficient observer and controller design for such bi-component agglomeration processes. Next, the states of the reduced order model are estimated in a Moving Horizon Estimation (MHE) approach. MHE is an optimization-based technique to estimate the unmeasurable state variables of a nonlinear dynamic system with noise in transition and measurement. One of the advantages of MHE over Extended Kalman Filter, the alternative approach in this area, is that it considers the physical constraints in its formulation. However, to offer this feature, MHE needs to solve a constrained nonlinear dynamic optimization problem which slows down the estimation process. In this work, we introduce and employ the Carleman approximation method in MHE design to accelerate the solution of the optimization problem. The Carleman method approximates the nonlinear system with a polynomial system at a desired accuracy level and recasts it in a bilinear form. By making this approximation, the KKT matrix required to solve the optimization problem becomes analytically available. Additionally, we perform a stability analysis for the proposed MHE design. As a result of this analysis, we derive a criterion for choosing an order of Carleman approximation procedure that ensures convergence of the scheme. Finally, some simulation results are included that show a significant reduction in the estimation time when the proposed method is employed.Moreover, a Stochastic Model Predictive Control (SMPC) design is employed to shape the distribution of the particles as required. The reduced-order model is employed in the SMPC formulation. The probabilistic constraints in this formulation keeps the variance of particles' drug concentration in an admissible range. To solve the resulting stochastic optimization problem, we first employ polynomial chaos expansion to obtain the Probability Distribution Function (PDF) of state variables using the uncertain variables' distributions. As a result, the original stochastic optimization problem for a particulate system is converted to a deterministic dynamic optimization. This representation lessens the computation burden of the controller and makes its real time application possible.Moisture content is a critical quality attribute in drying of pharmaceutical formulations. This work proposes a hybrid soft sensor for online real-time estimation of the product moisture in batch fluid bed dryers (FBD). Major applications include end-point detection, feed-back control, and process optimization resulting from increased process understanding. The proposed soft sensor utilizes commonly available measurements in a hybrid first-principle/empirical mathematical framework with few parameters to calibrate. Each parameter has a physical meaning in the model, enabling quantitative comparison of the drying dynamics of different formulations, products, and equipment. The soft sensor model requires experimental data from few batches for calibration, and historical data from production batches can be used for this purpose when available. Three case studies, two in pilot plant using different formulations and one using historical data from manufacturing batches, are presented in this work. The results support the proposed soft sensor model as a robust, practical and accurate method for online estimation of moisture in FBDs.

Formulation and Analytical Development for Low-Dose Oral Drug Products Springer Science & Business Media

The drying conditions of granules for tabletting prepared by the wet granulation process traditionally involve conduction, convection and radiation heat transfer. Despite various technological advances utilizing combinations of these conditions, the drying rates for pharmaceutical granules remain relatively high. Microwave drying is an alternative source of drying for pharmaceutical granules providing a faster drying rate, cost reduction benefits as well as reduced shrinkage and structural damage to granules. Polymorphic transformation of compounds in pharmaceutical products have become an important focus area since it can have disastrous economic, therapeutic and legal implications. The primary objective of this study was to use x-ray diffraction and fourier transform infrared spectral analysis to determine whether microwave drying would alter the polymorphic characteristics of carbamazepine contained in granules and tablets prepared by a wet granulation process, in comparison to convection tray drying. In addition, the compressed tablets from each drying method were objected to the British Pharmacopendial quality control standards to verify compliance.

Hydrophilic Matrix Tablets for Oral Controlled Release IGI Global

Only recently has bitterness control become of commercial importance to a food or pharmaceutical formulation chemist. Over the years, an increasing interest in more palatable food and beverage products with low fat and low sugar content has arisen, thus creating a market need for the control of bitterness perception. This is the first, comprehensive treatment of this subject in book form. Organized primarily by ingredients or processing approaches affecting the bitter taste reduction or inhibition, this thorough review includes an in-depth and thoroughly referenced review of mechanisms, ingredients and applications of bitter taste reduction or inhibition.

Formulation and Analytical Development for Low-Dose Oral Drug Products CRC Press

Iron Ore: Mineralogy, Processing and Environmental Issues summarizes recent, key research on the characterization of iron ores, including important topics such as beneficiation (separation and refining), agglomeration (e.g., production of pellets or powders), blast furnace technology for smelting, and environmental issues relating to its production. The text is an ideal reference on the topic during a time when iron ore production has increased significantly, driven by increasing demand from countries such as India and China. Provides a comprehensive overview of the global iron ore industry, exploring its characteristics and characterization Expert analysis of quality requirements for iron production, iron ore agglomeration technologies, environmental issues, and low-emission technologies Timely text to accompany the increased iron ore production occurring in developing countries like India and China

Controlled Release in Oral Drug Delivery Springer

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. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

Complementary and Alternative Approaches to Biomedicine John Wiley & Sons

This book had its origins in a meeting between two (relatively) young particle technology researchers on Rehobeth Beach in Delaware in 1992 near the holiday house of Reg Davies (then Director of the Particle Science and Technology Research Center in Dupont). As we played in the sand, we shared an excitement for developments in particle technology, especially particle characterization, that would lead operations such as granulation to be placed on a sound scientific and engineering footing. The immediate outcome from this interaction was the development of new industry short courses in granulation and related topics which we taught together both in Australia and North America. This book follows closely the structure and approaches developed in these courses, particularly the emphasis on particle design in granulation, where the impact of both formulation properties and process variables on product attributes needs to be understood and quantified. The book has been a long time in the making. We have been actively preparing the book for at least five years. Although the chapters have relatively good bibliographies, this book is not a review of the field. Rather it is an attempt by the authors to present a comprehensive engineering approach to granulator design, scale up and operation. It is exciting for us to see the explosion of research interest around the world in this area in the last five to seven years. Some of the most recent work will have to find its way into the second edition.

Theory and Practice in a Quality by Design Paradigm CRC Press

This Second Edition is an essential guide to preparing for FDA pre-approval inspections-taking into account current trends in FDA expectations and inspection activities, such as the GMPs of the 21st Century, quality systems-based approach to inspections, risk-based inspections, quality by design, process analytical technology, design space, etc. Th

Energy Research Abstracts CRC Press

A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.