Granulation Preparation Evaluation Control

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Developing Solid Oral Dosage Forms John Wiley & Sons
Continuous pharmaceutical manufacturing is currently receiving much interest from industry and regulatory authorities, with the joint aim of allowing rapid access of novel therapeutics and existing medications to the public, without compromising high quality. Research groups from different academic institutions have significantly contributed to this field with an immense amount of published research addressing a variety of topics related to continuous processing. The book is structured to have individual chapters on the different continuous unit operations involved in drug substance and drug product manufacturing. A wide spectrum of topics are covered, including basic principles of continuous manufacturing, applications of continuous flow chemistry in drug synthesis, continuous crystallization, continuous drying, feeders and blenders, roll compaction and continuous wet granulation.The underlying theme for each of these chapters is to present to the reader the recent advances in modeling, experimental investigations and equipment design as they pertain to each individual unit operation. The book also includes chapters on quality by design (QbD) and process analytical technology (PAT) for continuous processing, process control strategies including new concepts of quality-by-control (QbC), real-time process management and plant optimization, business and supply chain considerations related to continuous manufacturing as well as safety guidelines related to continuous chemistry. A separate chapter is dedicated to discussing regulatory aspects of continuous manufacturing, with description of current regulatory environment quality/GMP aspects, as well as regulatory gaps and challenges. Our aim from publishing this book is to make it a valuable reference for readers interested in this topic, with a desire to gain a fundamental understanding of engineering principles and mechanistic studies utilized in understanding and developing continuous processes. In addition, our advanced readers and practitioners in this field will find that the technical content of Continuous Pharmaceutical Processing is at the forefront of recent technological advances, with coverage

of future prospects and challenges for this technology.
Handbook of Pharmaceutical Granulation Technology Academic Press
Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology. Find out more about the series here.
Particulate Materials Cambridge University Press
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.
Nitroglycerin Sustained Release Tablet. Formulation Design and Evaluation 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.
Applications of Polymers in Drug Delivery John Wiley & Sons
Engineers encounter particles in a variety of systems. The particles are either naturally present or engineered into these systems. In either case these particles often significantly affect the behavior of such systems. This book provides a framework for analyzing these dispersed phase systems and describes how to synthesize the behavior of the population particles and their environment from the behavior of single particles in their local environments. Population balances are of key relevance to a very diverse group of scientists, including astrophysicists, high-energy physicists, geophysicists, colloid chemists, biophysicists, materials scientists, chemical engineers, and meteorologists. Chemical engineers have put population balances to most use, with applications in the areas of crystallization; gas-liquid, liquid-liquid, and solid-liquid dispersions; liquid membrane systems; fluidized bed reactors; aerosol reactors; and microbial cultures. Ramkrishna provides a clear and general treatment of population balances with emphasis on their wide range of applicability. New insight into population balance models incorporating random particle growth, dynamic morphological structure, and complex multivariate formulations with a clear exposition of their mathematical derivation is presented. Population Balances provides the only available treatment of the solution of inverse problems essential for identification of population balance models for breakage and aggregation processes, particle nucleation, growth processes, and more. This book is especially useful for process engineers interested in the simulation and control of particulate systems. Additionally, comprehensive treatment of the stochastic formulation of small systems provides for the modeling of stochastic systems with promising new areas of applications such as the design of sterilization systems and radiation treatment of cancerous tumors. - A clear and general treatment of population balances with emphasis on their wide range of applicability. Thus all processes involving solid-fluid and liquid-liquid dispersions, biological populations, etc. are encompassed - Provides new insight into population balance models incorporating random particle growth, dynamic morphological structure, and complex multivariate formulations with a clear exposition of their mathematical derivation - Presents a wide range of solution techniques, Monte Carlo simulation methods with a lucid exposition of their origin and scope for enhancing computational efficiency - An account of self-similar solutions of population balance equations and their significance to the treatment of data on particulate systems - The only available treatment of the solution of inverse problems essential for identification of population balance models for breakage and aggregation processes, particle nucleation and growth processes and so on - A comprehensive treatment of the stochastic formulation of small systems with several new applications
Drug Standards CRC Press

The book concentrates on powder flow properties, their measurement and applications. These topics are explained starting from the interactions between individual particles up to the design of silos. A wide range of problems are discussed – such as flow obstructions, segregation, and vibrations. The goal is to provide a deeper understanding of the powder flow, and to show practical solutions.

Laboratory Manual of Industrial Pharmacy I Springer Nature
Naturally occurring or manufactured through chemical and/or physical processes, particulate materials are substances consisting of individual particles which have significance to the global economy, society and environments. Due to the diversity and intrinsic nature, manufacturing, handling and processing of particulate materials still face numerous challenges. Aimed at addressing these challenges, this book contains a selection of papers discussing the state-of-the-art research in particulate materials science that were presented at the UK-China Particle Technology Forum III held at Birmingham, UK in 2011. Classified into four distinct topics namely synthesis, characterisation, processing and modelling, the chapters showcase the advances in these areas including a range of advanced synthesis methods for example, spray-pyrolysis, supercritical fluid synthesis assisted with ultrasound, continuous synthesis using supercritical water, hydrothermal synthesis of nano-particulate materials and jet milling. For characterisation, various methods for characterising particulate materials at both particle and system levels are introduced and how these properties affect the behaviour of particulate materials in various processes, such as inhalation, filling, and consolidation, are discussed. In the processing section, recent advances such as capsule filling, micro-dosing, dry granulation, roll compaction, milling, and more are presented. The last section concerns mathematical and numerical modelling in particulate materials, for which the book includes both analytical methods and advanced numerical methods, such as discrete element methods (DEM), computational fluid dynamics (CFD), lattice Boltzmann methods (LBM), coupled DEM/CFD and DEM/LBM, and their applications. Particulate Materials is aimed at research communities dealing with these diverse materials, and scientists and engineers in powder handling industries, such as pharmaceutical, food, fine chemical and detergents.

Physical Characterization of Pharmaceutical Solids CRC Press
This unique reference provides the first systematic coverage available in a single-source volume on the application of materials science techniques to the pharmaceutical field-offering a comprehensive program for the physical characterization of raw materials, drug substances, and formulated products.

Continuous Processing in Pharmaceutical Manufacturing
Univ of Wisconsin Press
Contains papers presented at the symposium of the same name.

Cumulated Index Medicus CRC Press
A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development, the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes. Continuous process manufacturing provides a proven solution. Among its many benefits are: minimized waste, energy consumption, and raw material use; the accelerated introduction of new drugs; the use of smaller production facilities with lower building and capital costs; the ability to monitor drug quality on a continuous basis; and enhanced process reliability and flexibility. Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency. This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both small-molecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles. Brings together the essential know-how for anyone working in drug manufacturing, as well as chemical, food, and pharmaceutical scientists working on continuous processing Covers chemical engineering principles, regulatory aspects, primary and secondary manufacturing, process analytical technology and quality-by-design Contains contributions from researchers in leading pharmaceutical companies, the FDA, and academic institutions Offers an extremely well-informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely, comprehensive, and authoritative, Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing.

The Science and Engineering of Granulation Processes
John Wiley & Sons
Fast Dissolving/Disintegrating Dosage Forms (FDDFs) have been commercially available since the late 1990s. FDDFs were initially available as orodispersible tablets, and later, as orodipsersible films for treating specific populations (pediatrics, geriatrics, and psychiatric patients). Granules, pellets and mini tablets are among latest additions to these dosage forms, which are still in the development pipeline. As drug delivery systems, FDDFs enable quicker onset of action, immediate drug delivery, and sometimes offer bioavailability benefits due to buccal/sublingual absorption. With time, FDDF have evolved to deliver drugs in a sustained and controlled manner. Their current market and application is increasing in demands with advances in age adapted dosage forms for different patients and changing regulatory requirements that warrant mandatory assessments of new drugs and drug products before commercial availability. This book presents detailed information about FDDFs from their inception to recent developments. Readers will learn about the technical details of various FDDF manufacturing methods, formulation aspects, evaluation and methods to conduct clinical studies. The authors also give examples of marketed fast disintegrating/dissolving drug products in US, Europe, Japan, and India. This reference is ideal for pharmacology students at all levels seeking information about this specific form of drug delivery and formulation.

Continuous Manufacturing of Pharmaceuticals Springer
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

Current Advances in Drug Delivery Through Fast Dissolving/Disintegrating Dosage Forms Springer Science & Business Media

Applications of Polymers in Drug Delivery, Second Edition, provides a comprehensive resource for anyone looking to understand how polymeric materials can be applied to current, new, and emerging drug delivery applications. Polymers play a crucial role in modulating drug delivery and have been fundamental in the successful development of many novel drug delivery systems. This book describes the development of polymeric systems, ranging from conventional dosage forms to the most recent smart systems. Regulatory and intellectual property aspects as well as the clinical applicability of polymeric drug delivery systems are also discussed. The chapters are organized by specific delivery route, offering methodical and detailed coverage throughout. This second edition has been thoroughly revised to include the latest developments in the field. This is an essential book for researchers, scientists, and advanced students, in polymer science, drug delivery, pharmacology/pharmaceuticals, materials science, tissue engineering, nanomedicine, chemistry, and biology. In industry, this book supports scientists, R&D, and other professionals, working on polymers for drug delivery applications. - Explains how polymers can be prepared and utilized for all major drug delivery routes - Presents the latest advances, including drug targeting, polymeric micelles and polymersomes, and the delivery of biologicals and nucleic acid therapeutics - Includes appendices with in-depth information on pharmaceutical properties of polymers and regulatory aspects

Design and Processing of Particulate Products CRC Press

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.

Handbook of Pharmaceutical Manufacturing Formulations Bentham Science Publishers

With contributions from biotechnologists and bioengineers, this ready reference describes the state of the art in industrial biopharmaceutical production, with a strong focus on continuous processes. Recent advances in single-use technology as well as application guidelines for all types of biopharmaceutical products, from vaccines to antibodies, and from bacterial to insect to mammalian cells are covered. The efficiency, robustness, and quality control of continuous production processes for biopharmaceuticals are reviewed and compared to traditional batch processes for a range of different production systems.

Hydrophilic Matrix Tablets for Oral Controlled Release Springer

The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloidons, emul

Continuous Pharmaceutical Processing GRIN Verlag

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.

XVIII International Coal Preparation Congress CRC Press

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

Powders and Bulk Solids John Wiley & Sons

This detailed volume addresses key issues and subtle nuances involved in developing hydrophilic matrix tablets as an approach to oral controlled release. It brings together information from more than five decades of research and development on hydrophilic matrix tablets and provides perspective on contemporary issues. Twelve comprehensive chapters explore a variety of topics including polymers (hypromellose, natural polysaccharides and polyethylene oxide) and their utilization in

hydrophilic matrices, critical interactions impacting tablet performance, in vitro physical and imaging techniques, and microenvironmental pH control and mixed polymer approaches, among others. In one collective volume, Hydrophilic Matrix Tablets for Oral Controlled Release provides a single source of current knowledge, including sections of previously unpublished data. It is an important resource for industrial and academic scientists investigating and developing these oral controlled release formulations.

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The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals Elsevier
The field of encapsulation, especially microencapsulation, is a rapidly growing area of research and product development. The Handbook of Encapsulation and Controlled Release covers the entire field, presenting the fundamental processes involved and exploring how to use those processes for different applications in industry. Written at a level comp