Pharmaceutical Excipients Properties Functionality And Applications In Research And Industry

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Developing Solid Oral Dosage Forms
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Pharmaceutical Manufacturing Handbook CRC Press
An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.
Developing Solid Oral Dosage Forms Springer Nature
HPLC for Pharmaceutical Scientists is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry. It provides a unified approach to HPLC with an equal and balanced treatment of the theory and practice of HPLC in the pharmaceutical industry. In-depth discussion of retention processes, modern HPLC separation theory, properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation. Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico-chemical point of view are provided. This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development. The latest advancements and trends in hyphenated and specialized HPLC techniques (LC-MS, LC-NMR, Preparative HPLC, High temperature HPLC, high pressure liquid chromatography) are also discussed.
Pharmaceutical Quality by Design Amer Pharmacists Assn
Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies
Excipient Applications in Formulation Design and Drug Delivery
BoD – Books on Demand
Modified Clay and Zeolite Nanocomposite Materials: Environmental and Pharmaceutical Applications retraces the most important knowledge gaps that the scientific community is facing, including a drawback of real-world applications. This valuable resource explores the novel applications of this group of nanomaterials that can be suitably surface-modified to obtain properties that can be applied in environmental and pharmaceutical fields. For example, modification with surfactants has given new motivation to the study of these materials by producing an inversion in the ion exchange behavior from cationic to anionic. This strategy has paved the way for new uses highlighted in this timely resource. Explores the combination of both minerals (clay and zeolite) together, with their application in two broad areas of emerging research Explains better utilization and applications for modified clay and zeolite through detailed comparative studies Consolidates information on the modification and tuning of clay and zeolite materials for novelty applications Helps users in the selection of materials, surface features, and other functionalization for diverse applications
Encyclopedia of Pharmaceutical Technology John Wiley & Sons
The global cost of health care is increasing year after year, and one of the ways governments and health care providers are looking to reduce cost is by reducing the cost of drug products. The generic industry is under tremendous pressure to remain competitive in the market place by reducing the cost of their product, with the main cost factor being the active pharmaceutical ingredient and some of the excipients used in the manufacture of the drug product. These companies are expected to follow the required guidelines set out by the international regulatory authorities and more specifically of the countries they intent to market their product in if they are planning to change the source of the material. These regulatory guidelines are general in nature with a focus on safety and efficacy and the evaluation of an alternate source of material by pharmaceutical companies varies greatly from company to company. The

evaluation is conducted mainly on the basis of chemical and physical data from the Certificate of Analysis comparing the current and alternate source to determine equivalency. Differences in process and critical processing parameters of the material can have significant impact on the behavior of the chemical, which may not be detectable through evaluation of the Certificates of Analysis. It is, therefore, critical to study properties that are not captured on the Certificate of Analysis, such as polymorphism, melting point, solubility, particle shape, packing tendencies among other aspects of the material that are important for the performance of the material in the drug product formulation and manufacturing process. The differences in these properties can have significant impact on the unit operations during the manufacturing process as well as the critical quality attributes and the stability of the drug product. The evaluation is conducted by utilizing various tools of analytical and process testing to determine the physical performance, physicochemical evaluation, chemical evaluation and functional performance evaluation for the active pharmaceutical ingredient and excipient. The evaluation of the Certificate of Analysis will also need to be more in depth, and go beyond the alternate source meeting the specifications as there can be significant differences with the results obtained even though they meet specification. It is important to identify these differences earlier in the evaluation stage and to assess the impact, if any, on the manufacturing process and the drug product prior to introducing the change. This study was conducted with active pharmaceutical ingredients selected based on the processing unit operations, such as direct compression process (metformin HCl), dry compaction (gabapentin), and hot-melt process (fenofibrate). The selection of the excipients was based on their functional properties, such as binders (copovidone NF/EP) and super disintegrant (croscarmellose Sodium NF/EP), allowing for evaluation with respect to differences in functionality if any, from the different sources. Additionally, the copovidone NF/EP is the binder in the gabapentin USP tablet formulation while the croscarmellose Sodium NF/EP is the super disintegrant in the fenofibrate EP/BP tablet formulation. An example of this challenge is that the evaluation of Certificate of Analysis for the materials supplied from two companies and two sources revealed differences in tests required for the two materials and a significant difference in some of the results obtained; however, both materials met their respective Certificate of Analysis specifications. Several tests beyond the Certificate of Analysis were performed and significant differences were also observed in many of these as well. The two sources were evaluated with respect to the compression process and the alternate source of material did show significant challenges during the tablet compression process and did not meet some of the in-process critical quality attributes test. The in-vitro performance for both sources were comparable, however, the recommendation will be not to proceed with the alternate source. There were many differences between the sources of all the materials evaluated including differences in particle size, morphology, moisture, manufacturing process and residual solvents among others. The impact on the manufacturing unit operation varies from no impact for the fenofibrate EP/BP materials, to not meeting the critical quality attributes for metformin HCl tablets with the new source of the active pharmaceutical ingredients. This study indicates the importance of a systematic evaluation of a material from an alternate source with respect to the performance of the manufacturing process, drug product, and their critical quality attributes; understanding the impact of these changes to the material and having the ability to correlate these to potential issues with the manufacturing process and drug product critical quality attributes prior to introducing an alternate source of material is critical.

Production and Processes Academic Press

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.

Bioactive Natural products in Drug Discovery Academic Press

A comprehensive, uniform guide to the uses, properties, and safety of pharmaceutical excipients and is an essential reference source for those involved in the development, production, control or regulation of pharmaceutical preparations. Features of this edition: Contains 210 excipient monographs; Collects together essential data of physical properties of excipients; Scanning electron photomicrographs included for many excipients; Contains information from various international sources; Also includes laboratory data determined specifically for the Handbook and personal observations; Contains information on the safe use and potential toxicity of the materials; All monographs in the Handbook are thoroughly cross-referenced and indexed so that excipients may be identified by either chemical, non-proprietary, or trade names; Written by over 120 pharmaceutical scientists expert in pharmaceutical formulation or excipient manufacture.

Particulate Materials John Wiley & Sons

Pharmaceutical ExcipientsProperties, Functionality, and Applications in Research and IndustryJohn Wiley & Sons

Excipient Applications in Formulation Design and Drug Delivery John Wiley & Sons

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.

Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems Academic Press

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. "

Functional Polymeric Composites Royal Society of Chemistry

The Handbook of Pharmaceutical Excipients contains essential data on the physical properties of excipients, their safe use and potential toxicity.

Strategy and Tactics for Chemistry, Manufacturing, and Controls CRC Press

Microsized and Nanosized Carriers for Nonsteroidal Anti-Inflammatory Drugs: Formulation Challenges and Potential Benefits provides a unique and complete overview of novel formulation strategies for improvement of the delivery of NSAIDs via encapsulation in microsized and nanosized carriers composed of different materials of natural and synthetic origin. This book presents the latest research on advances and limitations of both microsized and nanosized drug carriers and NSAIDs before discussing the formulation aspects of these drug carriers that are intended for oral, dermal, and transdermal administration of NSAIDs. In addition, functionality of these materials as potential excipients for microsized and nanosized carriers is discussed and debated. Practical solutions for improving effectiveness of these drugs are included throughout the book, making this an important resource for graduate students, professors, and researchers in the pharmaceutical sciences. Covers a wide range of microsized and nanosized carriers in one resource, including particulate carriers (microparticles, nanoparticles, and zeolites) and the soft colloidal carriers, such as micro-emulsions and nano-emulsions Presents the reader with various formulation approaches dependent on the characteristics of the material, model drug, and desired route of administration Approaches are based on the latest research in the area and formulation strategies may have broader applications to the encapsulation of other active pharmaceutical ingredients

Handbook of Pharmaceutical Wet Granulation Academic Press

Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach, reviewing applications on a case-by-case basis. Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers, in both academia and industry, with an interest in learning about CMC, and facilitating development and manufacture of peptide-based drugs.

Dosage Form Design Parameters Academic Press

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The

book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Pharmaceutical Quality by Design Academic Press

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.

Handbook of Pharmaceutical Excipients Academic 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

Pharmaceutical Theory and Practice John Wiley & Sons

Basic Fundamentals of Drug Delivery covers the fundamental principles, advanced methodologies and technologies employed by pharmaceutical scientists, researchers and pharmaceutical industries to transform a drug candidate or new chemical entity into a final administrable drug delivery system. The book also covers various approaches involved in optimizing the therapeutic performance of a biomolecule while designing its appropriate advanced formulation. Provides up-to-date information on translating the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various routes, such as orally, parenterally, transdermally or through inhalation Contains extensive references and further reading for course and self-study

HPLC for Pharmaceutical Scientists Springer

This book provides an overview of excipients, their functionalities in pharmaceutical dosage forms, regulation, and selection for pharmaceutical products formulation. It includes development, characterization methodology, applications, and up-to-date advances through the perspectives of excipients developers, users, and regulatory experts. Covers the sources, characterization, and harmonization of excipients: essential information for optimal excipients selection in pharmaceutical development Describes the physico-chemical properties and biological effects of excipients Discusses chemical classes, safety and toxicity, and formulation Addresses recent efforts in the standardization and harmonization of excipients

A Practical Guide from Candidate Drug Selection to Commercial Dosage Form CRC Press

Pain is both a symptom and a disease. It manifests in multiple forms and its treatment is complex. Physical, social, economic, and emotional consequences of pain can impair an individual's overall health, well-being, productivity, and relationships in myriad ways. The impact of pain at a population level is vast and, while estimates differ, the Centers for Disease Control and Prevention reported that 50 million U.S. adults are living in pain. In terms of pain's global impact, estimates suggest the problem affects approximately 1 in 5 adults across the world, with nearly 1 in 10 adults newly diagnosed with chronic pain each year. In recent years, the issues surrounding the complexity of pain management have contributed to increased demand for alternative strategies for treating pain. One such strategy is to expand use of topical pain medicationsâ€"medications applied to intact skin. This nonoral route of administration for pain medication has the potential benefit, in theory, of local activity and fewer systemic side effects. Compounding is an age-old pharmaceutical practice of combining, mixing, or adjusting ingredients to create a tailored medication to meet the needs of a patient. The aim of compounding, historically, has been to provide patients with access to therapeutic alternatives that are safe and effective, especially for people with clinical needs that cannot otherwise be met by commercially available FDA-approved drugs. Compounded Topical Pain Creams explores issues regarding the safety and effectiveness of the ingredients in these pain creams. This report analyzes the available scientific data relating to the ingredients used in compounded topical pain creams and offers recommendations regarding the treatment of patients.

Formulation Challenges and Potential Benefits Academic Press

Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com

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