Pharmaceutical Excipients Properties Functionality And Applications In Research And Industry

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Properties, Functionality, and Applications in Research and Industry
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Solid-State Properties of Pharmaceutical Materials
Handbook of Pharmaceutical Excipients
Handbook of Pharmaceutical Wet Granulation

LIVINGSTON KENDRA

Drug Product Design, Development, and Modeling 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. *Strategy and Tactics for Chemistry, Manufacturing, and Controls* 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. Chemical Engineering in the Pharmaceutical Industry CRC Press Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies examines recent advancements in pharmaceutical technology. The book discusses common formulation strategies, including the use of tools for statistical formulation optimization, Quality by design (QbD), process analytical technology, and the uses of various pharmaceutical biomaterials, including natural polymers, synthetic polymers, modified natural polymers, bioceramics, and other bioinorganics. In addition, the book covers rapid advancements in the field by providing a thorough understanding of pharmaceutical processes, formulation developments, explorations, and exploitation of various pharmaceutical biomaterials to formulate pharmaceutical dosage forms. Provides extensive information and analysis on recent

advancements in the field of pharmaceutical technology Includes contributions from global leaders and experts in academia, industry and regulatory agencies Uses high quality illustrations, flow charts and tables to explain concepts and text to readers, along with practical examples and research case studies

Basic Principles and Systems, Fifth Edition

CRC Press

Multivariate Analysis in the Pharmaceutical Industry provides industry practitioners with guidance on multivariate data methods and their applications over the lifecycle of a pharmaceutical product, from process development, to routine manufacturing, focusing on the challenges specific to each step. It includes an overview of regulatory guidance specific to the use of these methods, along with perspectives on the applications of these methods that allow for testing, monitoring and controlling products and processes. The book seeks to put multivariate analysis into a pharmaceutical context for the benefit of pharmaceutical practitioners, potential practitioners, managers and regulators. Users will find a resources that addresses an unmet need on how pharmaceutical industry professionals can extract value from data that is routinely collected on products and processes, especially as these

techniques become more widely used, and ultimately, expected by regulators. Targets pharmaceutical industry practitioners and regulatory staff by addressing industry specific challenges Includes case studies from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come

Properties, Functionality, and Applications in Research and Industry

Academic Press

This book highlights different natural products that are derived from the plants and microbes that have shown potential as the lead compounds against infectious diseases and cancer. Natural products represent an untapped source of strikingly diverse chemotypes with novel mechanisms of action and the potential to serve as anticancer and anti-infective agents. The book discusses a range of biotechnologically valuable bioactive compounds and secondary metabolites that have been derived from plant and microorganisms from various ecological niches. It also reviews the latest developments in the field of genomics, bioinformatics and industrial fermentation for harnessing the microbial products for commercial

applications. In turn, the book's closing section reviews important biotechnological applications of various natural products. Combining the expertise of specialists in this field, the book's goal is to promote the further investigation of natural sources for the development of standardized, safe and effective therapies.

Pharmaceutical Preformulation and Formulation Academic Press

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 John Wiley & Sons

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. "

Production and Processes Amer Pharmacists Assn

This book is about the chemical properties of starch. The book is a rich compendium driven by the desire to address the unmet needs of biomedical scientists to respond adequately to the controversy on the chemical properties and attendant reactivity of starch. It is a collective endeavor by a group of editors and authors with a wealth of experience and expertise on starch to aggregate the influence of qualitative and quantitative morphological,

chemical, and genetic properties of starch on its functionalities, use, applications, and health benefits. The chemical properties of starch are conferred by the presence, amount and/or quality of amylose and amylopectin molecules, granule structure, and the nature and amounts of the lipid and protein molecules. The implication of this is comprehensively dealt with in this book.

Dendrimer-Based Nanotherapeutics

Royal Society of Chemistry

To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue

A Practical Approach

Academic 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. **Order the Handbook of Pharmaceutical Excipients** CRC Press 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.

Excipient Applications in Formulation Design and Drug Delivery

John Wiley & Sons

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.

Parenteral Medications, Fourth Edition CRC 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. Bioactive Natural products in Drug Discovery CRC Press With over 100 illustrations, Volume 1 addresses the core disciplines of pharmaceutics (absorption, PK, excipients, tablet dosage forms, and packaging), and explores the challenges and paradigms of pharmaceutics. Key topics in Volume 1 include: • principles of drug absorption, chemical kinetics, and drug stability • pharmacokinetics • the effect of route of administration and distribution on drug action • in vivo imaging of dose forms: gamma scintigraphy, PET imaging NMR, MRI, etc. • powder technology • excipient design and characterization • preformulation • optimization techniques in pharmaceutical formulation and processing • disperse and surfactant systems • the solid state, tablet dosage forms, coating processes, and hard and soft shell capsules • parenteral products **Review of Select Ingredients for Safety, Effectiveness, and Use** Academic 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.

Dosage Form Design Parameters Amer Pharmacists Assn

This comprehensive handbook serves as a professional reference as well as a practitioner's guide to today's most complete and concise view of nanoscale networking and communications. It offers in-depth coverage of theory, technology, and

practice as they relate to established technologies and recent advancements. It explores practical solutions to a wide range of nanoscale networking and communications issues. Individual chapters, authored by leading experts in the field, address the immediate and long-term challenges in the authors' respective areas of expertise.

Formulation and Analytical Development for Low-Dose Oral Drug Products Royal Society of Chemistry

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 John Wiley & Sons

A practical guide to

Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of

applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

Developing Solid Oral Dosage Forms

Springer

This new work, Functional Polymeric Composites: Macro to Nanoscales, focuses on new challenges, findings, opportunities, and applications in the area of polymer composites. The chapters, written prominent researchers from academia, industry, and research institutes from around the world, present contemporary research and developments on advanced polymeric materials, including polymer blends, polymer electrolytes, bio-based polymer, polymer nanocomposites, etc. Several chapters also

cover the applications of the polymeric systems in current industry development and synthesis and characterization of the products.
Principles and Applications
Pharmaceutical ExcipientsProperties, Functionality, and Applications in Research and Industry
Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial

pharmacy and pharmaceutical technology.

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