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Handbook of Pharmaceutical Excipients **Handbook of Pharmaceutical Excipients Pharmaceutical Excipients Handbook of Pharmaceutical Excipients Excipient Toxicity and Safety** *Handbook of Pharmaceutical Excipients Plant Polysaccharides as Pharmaceutical Excipients* **Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems Investigation of Laser Sintering of Pharmaceutical Excipients for Oral Solid Dosage Forms Handbook of Pharmaceutical Excipients** *Profiles of Drug Substances, Excipients and Related Methodology* **Pharmaceutical Excipients** *Polyvinylpyrrolidone Excipients for Pharmaceuticals* **Excipient Toxicity and Safety** *Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017* **Oral Formulation Roadmap from Early Drug Discovery to Development** Controlled Drug Delivery **Active Pharmaceutical Ingredients in Synthesis** *The Ipec Good Manufacturing Practices Guide* Excipient Applications in Formulation Design and Drug Delivery Handbook of Cosmeceutical Excipients and their Safeties **Design and Manufacture of Pharmaceutical Tablets** Prof. of Drug Substances, Excipients and Related Methodology Significant Change Guide for Bulk Pharmaceutical Excipients 2000 Chemical Engineering in the Pharmaceutical Industry **Advances and Challenges in Pharmaceutical Technology Active Pharmaceutical Ingredients Pharmaceutical Quality by Design** *Japanese Pharmaceutical Excipients 2018* **Pharmaceutical Manufacturing Handbook JPE 1993** Certificate of Analysis Guide for Bulk Pharmaceutical Excipients 2000 **CRC Handbook of Food, Drug, and Cosmetic Excipients Formulation and Analytical Development for Low-Dose Oral Drug Products** CRC Handbook of Food, Drug, and Cosmetic Excipients **Analysis of Pharmaceuticals by Capillary Electrophoresis** Active Pharmaceutical Ingredients Martindale **Advanced Materials in Drug Release and Drug Delivery Systems Pharmaceutical Quality by Design**

Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems May 21 2022 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

Active Pharmaceutical Ingredients Nov 22 2019 To successfully bring an Active Pharmaceutical Ingredient (API) to market, many steps must be followed to ensure compliance with governmental regulations. Active Pharmaceutical Ingredients is an unparalleled guide to the development, manufacturing, and regulation of the preparation and use of APIs globally. Topics include: Safety, efficacy, and environmental/regulatory requirements Analysis of the recent movement of API manufacturing from the U.S. and Europe to countries such as India and China The FDA’s intensified foreign inspection program Multi-use and flexible design facilities The shift from maintenance scheduling to built-in reliability This second edition focuses on the quality control regulations for APIs that have been added or amended since the first edition. These

updates help ensure that pharmaceutical professionals and drug manufacturers meet the established and required guidelines set forth by the United States and international regulatory agencies.

Advances and Challenges in Pharmaceutical Technology Nov 03 2020 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

Certificate of Analysis Guide for Bulk Pharmaceutical Excipients 2000 Apr 27 2020

Significant Change Guide for Bulk Pharmaceutical Excipients 2000 Jan 05 2021

Japanese Pharmaceutical Excipients 2018 Jul 31 2020 This publication sets out the standards which have been established for the determination of the essence, preparation method, description, quality and storage of drug substances and products, as specified in general notices, general tests, processes and apparatus, and monographs detailing a total of 486 articles including 5 newly listed, 25 articles partly revised and one article deleted. Also known as JPE 2018, this publication is a companion publication to the Japanese pharmacopoeia (2017 main ed., ISBN 9784840813716) and to Japanese pharmaceutical codex.

Handbook of Pharmaceutical Excipients Jul 23 2022 The Handbook of Pharmaceutical Excipients is a comprehensive guide to the uses, properties and safety of pharmaceutical excipients and is an essential reference for those involved in the development, production, control or regulation of pharmaceutical preparations; The handbook collects together essential data on the physical properties of excipients as well as providing information on their safe use and potential toxicity. All monographs are also thoroughly cross-referenced and indexed to allow their identification by chemical, non-proprietary or trade names

Controlled Drug Delivery Aug 12 2021 In complex macromolecules, minor modifications can generate major changes, due to self-assembling capacities of macromolecular or supramolecular networks. Controlled Drug Delivery highlights how the multifunctionality of several materials can be achieved and valorized for pharmaceutical and biopharmaceutical applications. Topics covered in this comprehensive book include: the concept of self-assembling; starch and derivatives as pharmaceutical excipients; and chitosan and derivatives as biomaterials and as pharmaceutical excipients. Later chapters discuss polyelectrolyte complexes as excipients for oral administration; and natural semi-synthetic and synthetic materials. Closing chapters cover protein-protein associative interactions and their involvement in bioformulations; self-assembling materials, implants and xenografts; and provide conclusions and perspectives. Offers novel perspectives of a new concept: how minor alterations can induce major self-stabilization by cumulative forces exerted at short and long distances Gives guidance on how to approach modifications of biopolymers for drug delivery systems and materials for implants Describes structure-properties relationships in proposed excipients, drug delivery systems and biomedical materials

Chemical Engineering in the Pharmaceutical Industry Dec 04 2020 A guide to the development and manufacturing of

pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition: Contains 30new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying Presents updated and expanded example calculations Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industryf ocuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

Excipient Toxicity and Safety Aug 24 2022 This book reviews the history, regulatory status, pharmacopeial specifications, and harmonization of pharmaceutical excipients in the United States and Europe, and provides a comprehensive understanding of the current scientific basis for safety evaluation and risk assessment. Examines excipients as a unique class of products and explores new procedures for determining toxicity! A timely and unique addition to the pharmaceutical literature, containing over 570 citations that support and enhance the text, Excipient Toxicity and Safety identifies the differences between excipients (inactive ingredients), food ingredients, and drug products evaluates issues of dose administration, species selection, and study design for various routes of exposure provides detailed information on the historical uses of excipients in drug formulations clarifies the Safety Committee of the International Pharmaceutical Excipients Council's (IPEC) guidelines and technical specifications for conducting tests for each route of exposure explains how data generated in toxicity models are applied to identify hazards in drug formulations details exposure assessment to link hazard identification with risk considers the requirements and importance of purity specifications and much more! Excipient Toxicity and Safety is a blue-ribbon reference ideal for pharmacists; toxicologists; pharmacologists; analytical chemists; quality control, quality assurance, and regulatory compliance managers; and upper-level undergraduate and graduate students in these disciplines.

Martindale Oct 22 2019 This is thirty-fifth edition of Martindale, which provides reliable, and evaluated information on drugs and medicines used throughout the world. It contains encyclopaedic facts about drugs and medicines, with: 5,500 drug monographs; 128,000 preparations; 40,700 reference citations; 10,900 manufacturers. There are synopses of disease treatments which enables identification of medicines, the local equivalent and the manufacturer. It also Includes herbals, diagnostic agents, radiopharmaceuticals, pharmaceutical excipients, toxins, and poisons as well as drugs and medicines. Based on

published information and extensively referenced

Handbook of Cosmeceutical Excipients and their Safeties Apr 08 2021 Cosmeceuticals are the latest additions to the health industry and have an ever-expanding market. They are considered to be a marriage between cosmetics and drugs and are defined as preparations applied on the body that may modify the physiological functions of the skin. However, as more cosmeceuticals are being launched in the market and more types of drugs are incorporated into the formulation, the composition of cosmeceuticals is becoming more complex. Handbook of Cosmeceutical Excipients and their Safeties summarises the current evidence relating to cosmeceuticals' side effects and highlights the important information that practitioners and consumers need to know, as well as ways to avoid the adverse effects of the excipients. Handbook of Cosmeceutical Excipients and their Safeties includes chapters covering topics such as the history of cosmeceuticals and the laws that regulate them, skin permeation, carcinogenicity as a systemic adverse effect and dermatitis as a topical adverse effect. It concludes with an appendix that gives brief information on the potency and permeability of common ingredients in cosmeceuticals. The appendix aims to highlight the maximum allowable quantity of each ingredient to ensure product safety for consumers. The appendix was prepared by compiling the ingredients of 257 products containing more than 500 compounds, collected from a hospital pharmacy in Singapore. Focuses on the practical aspect of adverse effects from cosmeceuticals Explains the regulatory framework of cosmeceuticals Gives an idea of how excipients and drugs in cosmeceuticals enter the skin and methods of control

Prof. of Drug Substances, Excipients and Related Methodology Feb 06 2021 Profiles of Drug Substances, Excipients, and Related Methodology, Volume 46 contains comprehensive profiles of five drug compounds: Darunavir, Bisoprolol, Betaxolol, Rabeprazole and Irbesartan. In addition, the work contains a chapter reviewing Bioassay Methods and Their Applications in Herbal Drug Research. The comprehensive reviews in the book cover all aspects of drug development and the formulation of drugs, helping readers understand how the drug development community remains essential to all phases of pharmaceutical development. In addition, this work answers why such profiles are of immeasurable importance to workers in the field. The scope of the Profiles series encompasses review articles and database compilations that fall within one or more of the following five broad categories: Physical Profiles of Drug Substances and Excipients, Analytical Profiles of Drug Substances and Excipients, ADME Profiles of Drug Substances and Excipients, Methodology Related to the Characterization of Drug Substances and Excipients, and Methods of Chemical Synthesis. Contains contributions from leading authorities Presents an excellent overview on the physical, chemical and biomedical properties of some regularly prescribed drugs Includes a cumulative index in each volume

Polyvinylpyrrolidone Excipients for Pharmaceuticals Dec 16 2021 The book describes the properties, analytical methods and the applications of different polyvinylpyrrolidone excipients (povidone, crospovidone, copovidone etc.) for use in pharmaceutical preparations. This group of excipients is one of the most important excipients used in modern technology to produce drugs. The book is intended for all persons working in the research, development and quality control of drugs. It gives a survey of all applications in solid, liquid and semisolid dosage forms including many drug formulation examples and more than 600 references to the literature.

Handbook of Pharmaceutical Excipients Sep 25 2022 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.

Pharmaceutical Quality by Design Aug 20 2019 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

Pharmaceutical Excipients Oct 26 2022 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

Plant Polysaccharides as Pharmaceutical Excipients Jun 22 2022 Plant Polysaccharides as Pharmaceutical Excipients explores innovative techniques and applications of plant-derived polysaccharides as pharmaceutical excipients. Plant polysaccharides are sustainable, renewable and abundantly available, offering attractive properties in terms of water solubility, swelling ability, non-toxicity and biodegradability. These qualities have resulted in extensive exploration into their applications as excipients in a variety of pharmaceutical dosage forms. This book takes a comprehensive, application-oriented approach, drawing on the very latest research that includes sources, classification and extraction methods of plant polysaccharides. Subsequent chapters focus on plant polysaccharides for individual pharmaceutical applications, enabling the reader to understand their preparation for specific targeted uses. Throughout the book, information is supported by illustrations, chemical structures, flow charts and data tables, providing a clear understanding. Finally, future perspectives and challenges are reviewed and discussed. Explains sources, classifications, extraction methods and biocompatibility of plant polysaccharides Guides the reader through properties and preparation methods of plant polysaccharides as pharmaceutical excipients Covers a broad range of cutting-edge applications, with each chapter targeting a specific use

Analysis of Pharmaceuticals by Capillary Electrophoresis Dec 24 2019 Dieser erste Titel einer ganzen Serie von anwendungsbezogenen Handbüchern zur

Kapillarelektrophorese beschäftigt sich mit der Analytik von pharmazeutischen Substanzen. Dabei werden verschiedene Techniken praxisnah erläutert. Jeder, der im Labor - ob wissenschaftlich oder praxisnah - mit der Analyse von oft chiralen Pharmazeutika konfrontiert ist, wird viele Hinweise und Tips für seine Arbeit finden.USP: Einzige Monographie zur Analyse von Pharmazeutika mit CE This book describes the current state of the art for the analysis of pharmaceuticals by capillary electrophoresis and contains several hundred references to specific applications and methods. The main purpose of the book is to present the application possibilities of CE an therefore tabulated application data are provided. Chapters of the book are devoted to providing details of individual application areas such as chiral analysis, determination of drug related impurities, determination of drug counter-ions, drug residue monitoring and main component assay. An introductory chapter provides theoretical background to CE an related techniques. A chapter is dedicated to capillary electrochromatography which highlights the importance this technique currently possesses. Successful regulatory acceptance of CE methods is also described. A comprehensive chapter covers method validation aspects. Other chapters include discrete areas such as the use of non-aqueous solvents, forensic applications of CE, the application of experimental designs, determination of drugs in biofluids, and the analysis of vitamins by CE.

Pharmaceutical Quality by Design Sep 01 2020 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.

Active Pharmaceutical Ingredients in Synthesis Jul 11 2021 Presents the most effective catalytic reactions in use today, with a special focus on process intensification, sustainability, waste reduction, and innovative methods This book demonstrates the importance of efficient catalytic transformations for producing pharmaceutically active molecules. It presents the key catalytic reactions and the most efficient catalytic processes, including their significant advantages over compared previous methods. It also places a strong emphasis on asymmetric catalytic reactions, process intensification (PI), sustainability and waste mitigation, continuous manufacturing processes as enshrined by continuous flow catalysis, and supported catalysis. Active Pharmaceutical Ingredients in Synthesis: Catalytic Processes in Research and Development offers chapters covering: Catalysis and Prerequisites for the Modern Pharmaceutial Industry Landscape; Catalytic

Process Design - The Industrial Perspective; Hydrogenation, Hydroformylation and Other Reductions; Oxidation; ; Catalytic Addition Reactions; Catalytic Cross-Coupling Reactions; Catalytic Metathesis Reactions; Catalytic Cycloaddition Reactions: Coming Full-Circle; Catalytic Cyclopropanation Reactions; Catalytic C-H insertion Reactions; Phase Transfer Catalysis; and Biocatalysis. -Provides the reader with an updated clear view of the current state of the challenging field of catalysis for API production -Focuses on the application of catalytic methods for the synthesis of known APIs -Presents every key reaction, including Diels-Alder, CH Insertions, Metal-catalytic coupling-reactions, and many more -Includes recent patent literature for completeness Covering a topic of great interest for synthetic chemists and R&D researchers in the pharmaceutical industry, Active Pharmaceutical Ingredients in Synthesis: Catalytic Processes in Research and Development is a must-read for every synthetic chemist working with APIs.

Excipient Applications in Formulation Design and Drug Delivery May 09 2021 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.

Handbook of Pharmaceutical Excipients Nov 27 2022 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.

Oral Formulation Roadmap from Early Drug Discovery to Development Sep 13 2021 Detailing formulation approaches by stage of discovery to early development, this book gives a “playbook” of practical and efficient strategies to formulate drug candidates with the least chance of failing in clinical development. • Comes from contributing authors with experience developing formulations on the frontlines of the pharmaceutical industry • Focuses on pre (or non-) clinical and early stage development, the phases where most compounds are used in drug research • Features case studies to illustrate practical challenges and solutions in formulation selection • Covers regulatory filing, drug metabolism and physical and chemical properties, toxicology formulation, biopharmaceutics classification system (BCS), screening approaches, early stage clinical formulation development, and outsourcing

Profiles of Drug Substances, Excipients and Related Methodology Feb 18 2022 Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical

profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Presents comprehensive reviews covering all aspects of drug development and formulation of drugs Profiles creatine monohydrate and fexofenadine hydrochloride, as well as five others Meets the information needs of the drug development community

Advanced Materials in Drug Release and Drug Delivery Systems Sep 20 2019 Development of new drug molecules is costly and requires longitudinal, wide-ranging studies; therefore, designing advanced pharmaceutical formulations for existing and well-known drugs seems to be an attractive device for the pharmaceutical industry. Properly formulated drug delivery systems can improve pharmacological activity, efficacy and safety of the active substances. Advanced materials applied as pharmaceutical excipients in designing drug delivery systems can help solve problems concerning the required drug release—with the defined dissolution rate and at the determined site. Novel drug carriers enable more effective drug delivery, with improved safety and with fewer side effects. Investigations concerning advanced materials represent a rapidly growing research field in material/polymer science, chemical engineering and pharmaceutical technology. Exploring novel materials or modifying and combining existing ones is now a crucial trend in pharmaceutical technology. Eleven articles included in the the Special Issue “Advanced Materials in Drug Release and Drug Delivery Systems” present the most recent insights into the utilization of different materials with promising potential in drug delivery and into different formulation approaches that can be used in the design of pharmaceutical formulations.

The Ipec Good Manufacturing Practices Guide Jun 10 2021

Handbook of Pharmaceutical Excipients Mar 19 2022 Provides data on the additives used to convert pharmacologically active compounds into dosage forms suitable for administration to patients. Data includes: nonproprietary names, functional category, synonyms, chemical names and CAS Registry number, empirical formula, molecular weight, structural formula, commercial availability, method of manufacture,description, pharmacopeial specifications, typical properties, stability and storage conditions, incompatibilities, safety, handling precautions, regulatory acceptance, applications in pharmaceutical formulation or technology, use, related substances, comments, and specific references.

JPE 1993 May 29 2020

Formulation and Analytical Development for Low-Dose Oral Drug Products Feb 24 2020 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.

Excipient Toxicity and Safety Nov 15 2021 This book reviews the history, regulatory status, pharmacopeial specifications, and harmonization of pharmaceutical excipients in the United States and Europe, and provides a comprehensive understanding of the current scientific basis for safety evaluation and risk assessment. Examines excipients as a unique class of products and explores new procedures for determining toxicity! A timely and unique addition to the pharmaceutical literature, containing over 570 citations that support and enhance the text, Excipient Toxicity and Safety identifies the differences between excipients (inactive ingredients), food ingredients, and drug products evaluates issues of dose administration, species selection, and study

design for various routes of exposure provides detailed information on the historical uses of excipients in drug formulations clarifies the Safety Committee of the International Pharmaceutical Excipients Council's (IPEC) guidelines and technical specifications for conducting tests for each route of exposure explains how data generated in toxicity models are applied to identify hazards in drug formulations details exposure assessment to link hazard identification with risk considers the requirements and importance of purity specifications and much more! Excipient Toxicity and Safety is a blue-ribbon reference ideal for pharmacists; toxicologists; pharmacologists; analytical chemists; quality control, quality assurance, and regulatory compliance managers; and upper-level undergraduate and graduate students in these disciplines.

Investigation of Laser Sintering of Pharmaceutical Excipients for Oral Solid Dosage Forms Apr 20 2022

CRC Handbook of Food, Drug, and Cosmetic Excipients Mar 27 2020 CRC Handbook of Food, Drug, and Cosmetic Excipients provides a comprehensive summary of toxicological issues regarding inactive ingredients in pharmaceutical products, cosmetic products, and food additives. Background information on regulations and labeling requirements for each type of product is provided, and 77 articles critically review human and animal data pertinent to a variety of agents and makes judgments regarding the clinical relevance. The book also identifies at-risk populations, such as neonates, patients with renal failure, and atopic patients. Inactive common pharmaceutical agents and/or foods containing certain ingredients are listed to help physicians counsel hypersensitive patients who must avoid products containing these excipients.

Active Pharmaceutical Ingredients Oct 02 2020 Focusing on the three most critical components that successfully bring an API to market-process development, manufacturing, and governmental regulation and approval-this reference serves as a step-by-step guide to the planning and clear understanding of the bulk manufacturing of APIs. This guide offers current and timely discussions of the process development cycle, design engineering, the approval process, quality control and assurance, and validation, as well as plant manufacturing activities including materials management, maintenance, and safety.

Design and Manufacture of Pharmaceutical Tablets Mar 07 2021 Design and Manufacture of Pharmaceutical Tablets offers real world solutions and outcomes of formulation and processing challenges of pharmaceutical tablets. This book includes numerous practical examples related to actual formulations that have been validated and marketed and covers important data in the areas of stability, dissolution, bioavailibity and processing. It provides important background and theoretical information on design and manufacturing and includes a full section dedicated to design experimental methodology and statistics. In addition, this book offers a a general discussion of excipients used in proper tablet design along with practical examples related to excipients. Drug development scientists in industry and academia, as well as students in the pharmaceutical sciences will greatly benefit from the practical knowledge and case examples provided throughout this book. Incorporates important mathematical models and computational applications Includes unique content on central composite design and augmented simplex lattice Provides background on important design principles with emphasis on quality-based design (QBD) of pharmaceutical dosage forms

Pharmaceutical Excipients Jan 17 2022 Meeting the need for a hands-on guide elucidating the role of molecular spectroscopy in the physical characterization of pharmaceutical solids, two experts from the industry gather theoretical discussions of infrared, Raman, and nuclear magnetic resonance spectroscopy. They provide recommendations on spectral data acquisition techniques and include 600 spectra for 300 of the most commonly used excipients. Complete with references, equations, tables, and a CAS registry number index, the book covers the drug development process, including chemical identification of substances, investigative studies, competitor analysis, problem solving

activities, reproduction of spectral data, and more.

CRC Handbook of Food, Drug, and Cosmetic Excipients Jan 25 2020 CRC Handbook of Food, Drug, and Cosmetic Excipients provides a comprehensive summary of toxicological issues regarding inactive ingredients in pharmaceutical products, cosmetic products, and food additives. Background information on regulations and labeling requirements for each type of product is provided, and 77 articles critically review human and animal data pertinent to a variety of agents and makes judgments regarding the clinical relevance. The book also identifies at-risk populations, such as neonates, patients with renal failure, and atopic patients. Inactive common pharmaceutical agents and/or foods containing certain ingredients are listed to help physicians counsel hypersensitive patients who must avoid products containing these excipients.

Pharmaceutical Manufacturing Handbook Jun 29 2020 This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Handbook of Pharmaceutical Excipients Dec 28 2022 The Handbook of Pharmaceutical Excipients contains essential data on the physical properties of excipients, their safe use and potential toxicity.

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017 Oct 14 2021 Commonly known as the Orange Guide, this book remains an essential reference for all manufacturers and distributors of medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines.