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Handbook of Pharmaceutical Excipients Pharmaceutical Excipients Handbook of Pharmaceutical Excipients Excipient Applications in Formulation Design and Drug Delivery Handbook of Pharmaceutical Excipients Handbook of Pharmaceutical Excipients Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems Pharmaceutical Excipients Excipient Toxicity and Safety Plant Polysaccharides as Pharmaceutical Excipients Handbook of Pharmaceutical Excipients Excipient Toxicity and Safety The Effects of Pharmaceutical Excipients on Drug Disposition Controlled Drug Delivery Profiles of Drug Substances, Excipients and Related Methodology Pharmaceutical Excipients 2001 Handbook of Pharmaceutical Excipients Prof. of Drug Substances, Excipients and Related Methodology Pharmaceutical Excipients The Role of Pharmaceutical Excipients in the Solid-state Degradation of Gabapentin Pharmaceutical Excipients The in Vivo Effects of Pharmaceutical Excipients on Gastrointestinal Transit and Drug Absorption The Effect of Pharmaceutical Excipients on Small Intestinal Transit Kinetic and Thermodynamic Investigation of a Series of Pharmaceutical Excipients Natural Polymers for Pharmaceutical Applications Oral Formulation Roadmap from Early Drug Discovery to Development Roll Compaction of Pharmaceutical Excipients Handbook of Pharmaceutical Excipients Pharmaceutical Suspensions Guidance for Industry Pharmaceutical Excipients Advanced Materials in Drug Release and Drug Delivery Systems Roll Compaction of Pharmaceutical Excipients and Prediction Using Intelligent Software Polyvinylpyrrolidone Excipients for Pharmaceuticals Rationalising the Selection of Pharmaceutical Excipients for the Formulation of Amorphous Solid Dispersions Polyvinylpyrrolidone Excipients for Pharmaceuticals Pharmaceutical Formulation Japanese Pharmaceutical Excipients 2018 Pharmaceutical Excipients Formulation and Analytical Development for Low-Dose Oral Drug Products

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 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. 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 Formulation is a key step in the drug design process, where the active drug is combined with other substances that maximise the therapeutic potential, safety and stability of the final medicinal product. Modern formulation science deals with biologics as well as small molecules. Regulatory and quality demands, in addition to advances in processing technologies, result in growing challenges as well as possibilities for the field. Pharmaceutical Formulation provides an up to date source of information for all who wish to understand the principles and practice of formulation in the drug industry. The book provides an understanding of the links between formulation theory and the practicalities of processing in a commercial environment, giving researchers the knowledge to produce effective pharmaceutical products that can be approved and manufactured. The first chapters introduce readers to different dosage forms, including oral liquid products, topical products and solid dosage forms such as tablets and capsules. Subsequent chapters cover pharmaceutical coatings, controlled release drug delivery and dosage forms designed specifically for paediatric and geriatric patients. The final chapter provides an introduction to the vital role intellectual property plays in drug development. Covering modern processing methods and recent changes in the regulatory and quality demands of the industry, Pharmaceutical Formulation is an essential, up to date resource for students and researchers working in academia and in the

pharmaceutical industry. 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. 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 The suspension dosage form has long been used for poorly soluble active ingre- ents for various therapeutic indications. Development of stable suspensions over the shelf life of the drug product continues to be a challenge on many fronts. A good understanding of the fundamentals of disperse systems is essential in the development of a suitable pharmaceutical suspension. The development of a s- pension dosage form follows a very complicated path. The selection of the proper excipients (surfactants, viscosity imparting agents etc.) is important. The particle size distribution in the finished drug product dosage form is a critical parameter that significantly impacts the bioavailability and pharmacokinetics of the product. Appropriate analytical methodologies and instruments (chromatographs, visco- ters, particle size analyzers, etc.) must be utilized to properly characterize the s- pension formulation. The development process continues with a successful scale-up of the manufacturing process. Regulatory agencies around the world require cli- cal trials to establish the safety and efficacy of the drug product. All of this devel- ment work should culminate into a regulatory filing in accordance with the regulatory guidelines. Pharmaceutical Suspensions, From Formulation Development to Manufacturing, in its organization, follows the development approach used widely in the pharmaceutical industry. The primary focus of this book is on the classical disperse system – poorly soluble active pharmaceutical ingredients s- pended in a suitable vehicle. 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. 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. This is the second edition of a work on pharmaceutical excipients. It has been expanded and revised to include 203 monographs for pharmacopoeital and non-pharmacopoeital excipients. The appendices include a substantial suppliers' directory. All the physical properties of excipients are included. 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 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. Many polymers derived from various marine sources and microorganisms possess some important biological properties such as biocompatibility, biodegradability, and bioadhesivity that make them attractive as pharmaceutical excipients in various pharmaceutical dosage forms. Moreover, these polymers can be

modified physically and/or chemically to improve their biomaterial properties. In this volume, Natural Polymers for Pharmaceutical Applications, Volume 2: Marine- and Microbiologically Derived Polymers, looks at how these polymers have been explored and exploited for pharmaceutical uses, such as in tablets, microparticles, nanoparticles, ophthalmic preparations, gels, emulsions, suspensions, etc. Some commonly used marine- and microbiologically derived polymers used as pharmaceutical excipients include alginates, agar-agar, gellan gum, carrageenan; chitosan, xanthan gum, and others. The book focuses on important recent advances from experts around the world on marine-derived polysaccharides and pharmaceutical applications of alginates, agar-agar, gellan gum, carrageenan, chitosan derivatives, xanthan gum. 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 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. 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. Drug instability in solid dosage forms includes chemical or physical processes involving covalent or polymorphic transformations wherein different polymorphs possess crystal structure differences. Gabapentin chemically degrades by intramolecular cyclization to gabapentin-lactam (lactam) in the solid-state. Additionally, gabapentin undergoes polymorphic solid-state transformations. A kinetic model was developed to describe the environmental and excipient effects on chemical and physical instability associated with milling induced stress and subsequent storage under controlled temperature and humidity conditions. Reaction mixtures were generated by co-milling gabapentin Form II with various excipients. The effects of environmental conditions were studied by storing reaction mixtures at 40-60 ?ðC and 5-50 %RH. The chemical and polymorphic compositions of the reaction mixtures were measured as a function of time using a combination of chromatographic method, 13C ssNMR and XRPD. Degradation models that describe the relationship between polymorphs and degradation product in a series of sequential or parallel steps were devised based on analysis of the resultant concentration time profiles. Model parameters were estimated using non-linear regression and Bayesian methods and evaluated in terms of their quantitative relationship to compositional and conditional variations. In reaction mixtures composed of co-milled gabapentin and excipients, gabapentin was found to exist in three forms: anhydrous polymorph II and III and gabapentin-lactam. A fourth form (II*) was observed based on initial degradation kinetics and was hypothesized to be a crystal-disordered form generated by mechanical stress. The effect of environment moisture was to decrease the net rate of lactam formation by facilitating polymorphic transformation kinetics and crystal annealing. However, excipient blocked the catalytic moisture effect on polymorphic transformations. 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. 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 The Handbook of Pharmaceutical Excipients collects together essential data on the physical properties of excipients as well as providing information on their safe use and applications. All of the 400+ monographs are also thoroughly cross-referenced and indexed to allow their identification by chemical, non-proprietary or trade names. It is internationally recognised as the

authoritative source of information on pharmaceutical excipients and a comprehensive guide to uses, properties and safety. Monographs benefit from a standardized, easy-to-use template and include: Pharmacopeial information from the UK, Europe, Japan and the United States where relevant Non-proprietary names and synonyms Chemical name, CAS Registry number, empirical formula, molecular weight Functional category, applications and incompatibilities Material description and typical properties Safety, stability, storage and handling information Method of manufacture Related substances Primary references Editorial comments Authors details and revision date Changes to this new edition: Contains revised and updated monographs 20 + new monographs including amino acids Arginine, Proline and Asparagine Includes newly added Raman spectra for many excipients New chapter content including information on excipients in oral solid dose formulations, and pediatric formulations 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 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. 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. 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 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. 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! 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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. 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.