

Japanese Pharmaceutical Excipients

Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies. The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update. This cutting-edge resource includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission. The format, specification, and technical requirements of the e-CTD, the electronic version of CTD, are also thoroughly discussed. The book is organized into six highly practical segments: Part I: CTD, eCTD, Module 1, and Environmental Risk Assessment Part II: CTD Summaries Part III: Quality Topics Part IV: Nonclinical Topics Part V: Clinical Topics Part VI: Other Topics (including drug-device combination products) This text is a must-have for those in the pharmaceutical industry determining regulatory requirements for the major world markets in Europe, the US, Canada, and Japan.

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.

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 toxicological monograph's in this volume summarize the safety data on a number of food additives: Beeswax Candelilla wax Quillaia extract Type 1 and 2 Phospholipase from fusarium venenatum expressed in Aspergillus oryzae Calcium L-5 methyltetrahydrofolate (L-5_MTHF) and Pullulan (Pullulan P1-20). Monograph's on seven groups of related flavouring agents evaluated by the Procedure for the Safety Evaluation of Flavouring Agents are also included. Pharmaceutical Dosage Forms: Capsules covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation.

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Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination and provide a reference for the practitioner. The second edition reflects the Body of Knowledge which was updated in 2015. This edition has also incorporated additional information including updated references. The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight. This handbook covers compliance with good manufacturing practices (GMPs), as regulated and guided by national and international agencies for the pharmaceutical industry. It covers finished human and veterinary drugs and biologics, and combination devices, as well as their component raw materials (including active pharmaceutical ingredients (APIs) and excipients), and packaging and labeling operations. The Japanese Pharmacopoeia 17th edition (JP XVII) English translation is fully endorsed by the society of the Japanese Pharmacopoeia. It defines the specifications, criteria and standard test methods necessary to properly ensure the quality of medicines in Japan. The Japanese language edition was effective from 1st April 2016. Key features: -General Notices, General Rules for Crude Drugs, General Rules for Preparations: revised and expanded. -Official monographs: 76 new monographs and 473 revised monographs. -General tests, processes and apparatus: 23 new standards and 10 revised standards. -Infrared reference spectra: 21 new spectra and 2 revised spectra. -Ultraviolet-visible reference spectra: 14 new spectra and 2 revised spectra This title supersedes the Japanese Pharmacopoeia 16th edition (ISBN 9784840812023), as well as JP 16th edition Supplement I (ISBN 9784840812382) and JP 16th edition Supplement II (ISBN 9784840812832). The JP aims to: 1.Include all drugs which are important from the viewpoint of health care and medical treatment. 2.Make qualitative improvement by introducing the latest science and technology. 3.Promote internationalization. Make prompt partial revision as necessary and facilitating smooth administrative operation. Ensure transparency regarding the revision, and disseminating the JP to the public.

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

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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.

Use of polymers has become indispensable in the field of drug delivery. Polymers play a crucial role in modulating drug delivery to exploit maximum therapeutic benefits and have been fundamental in the successful development of several novel drug delivery systems that are now available. This book provides details of the applications of polymeric drug delivery systems that will be of interest to researchers in industries and academia. It describes the development of polymeric systems ranging from the conventional dosage forms up to the most recent smart systems. The regulatory and intellectual property aspects as well as the clinical applicability of polymeric drug delivery systems are also discussed. Each different drug delivery route is discussed in a separate chapter of the book. All major routes of drug delivery have been covered to provide the reader with a panoramic as well as an in-depth view of the developments in polymer-based drug delivery systems. Appendices are included which incorporate useful pharmaceutical properties of the polymers and important polymeric applications for various drug delivery routes.

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.

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.

This three-volume set of *Pharmaceutical Dosage Forms: Parenteral Medications* is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume three presents:

- An in-depth discussion of regulatory requirements, quality assurance, risk assessment and mitigation, and extractables/leachables.
- Specific chapters on parenteral administrations devices, injection site pain assessment, and parenteral product specifications and stability testing.
- Forward-thinking discussions on the future of parenteral product manufacturing, and siRNA delivery systems.
- New chapters covering recent developments in the areas of visual inspection, quality by design (QbD), process analytical technology (PAT) and rapid microbiological methods (RMM), and validation of drug product manufacturing process.

This title focuses on the comprehension of the properties of water in foods, enriched by the approaches from polymer and materials sciences, and by the advances of analytical techniques. The International Symposium on the Properties of Water (ISOPOW) promotes the exchange of knowledge between scientists involved in the study of food materials and scientists interested in water from a more basic point of view and the dialogue between academic and industrial scientists/technologists. This comprehensive book covers the topics presented at the 10th ISOPOW held in Bangkok, Thailand in 2007, including water dynamics in various systems, the role of water in functional food and nano-structured biomaterials. Special features include: Latest findings in the properties of water in food, pharmaceutical and biological systems Coverage of the 10th International Symposium on the Properties of Water (ISOPOW) Includes water

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tests, processes and apparatus, and monographs detailing a total of 479 articles including 44 newly listed, 31 articles partly revised and one article deleted. Also known as JPE 2004, this publication is a companion publication to the Japanese pharmacopoeia (2001 main ed., ISBN 4840806721) and to Japanese pharmaceutical codex.

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.

In this volume, the authors discuss the many significant challenges currently faced in biotechnology dosage form development, providing guidance, shared experience and thoughtful reflection on how best to address these potential concerns. As the field of therapeutic recombinant therapeutic proteins enters its fourth decade and the market for biopharmaceuticals becomes increasingly competitive, companies are increasingly dedicating resources to develop innovative biopharmaceuticals to address unmet medical needs. Often, the pharmaceutical development scientist is encountering challenging pharmaceutical properties of a given protein or by the demands placed on the product by stability, manufacturing and preclinical or clinical expectations, as well as the evolving regulatory expectations and landscape. Further, there have been new findings that require close assessment, as for example those related to excipient quality, processing, viscosity and device compatibility and administration, solubility and opalescence and container-closure selection. The literature varies widely in its discussion of these critical elements and consensus does not exist. This topic is receiving a great deal of attention within the biotechnology industry as well as with academic researchers and regulatory agencies globally. Therefore, this book is of interest for business leaders, researchers, formulation and process development scientists, analytical scientists, QA and QC officers, regulatory staff, manufacturing leaders and regulators active in the pharmaceutical and biotech industry, and expert reviewers in regulatory agencies.

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

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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.

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use, in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia - updating mechanism for the section on radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles; Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.

Describes the chemical and physical properties of pharmaceutical excipients. Each monograph contains nonproprietary names, synonyms, chemical name and CAS registry number, empirical formula and molecular weight, structural formula, functional category, applications in pharmaceutical formulation or technology, description, pharmacopeial specifications, typical properties, stability and storage conditions, incompatibilities, method of manufacture, safety, handling precautions, regulatory status, pharmacopeias, related substances, comments, specific references, general references, and authors.

This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as

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supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase—appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

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