Pharmaceutical Dosage Forms: Parenteral Medications

Third Edition

Volume 2: Facility Design, Sterilization and Processing







informa

Edited by Sandeep Nema John D. Ludwig

Pharmaceutical Dosage Forms Parenteral Medications Volume 2

Herbert Lieberman, Martin Rieger, Gilbert S. Banker

Pharmaceutical Dosage Forms Parenteral Medications Volume 2:

Pharmaceutical Dosage Forms - Parenteral Medications Sandeep Nema, John D. Ludwig, 2016-04-19 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 Dosage Forms: Parenteral Medications, Third Edition Sandeep Nema, John D. Ludwig, 2010 A historical perspective of injectable drug therapy common routes of administration and biopharmaceutics of NCEs and NBEs An in depth discussion on the preformulation and formulation of small and large molecules including ophthalmic dosage forms A presentation of parenteral primary packaging options glass and plastic containers as well as elastomeric closures A definitive chapter on container closure integrity New chapters on solubility and solubilization formulation of depot delivery systems and biophysical biochemical characterization of proteins Library of Congress Pharmaceutical Dosage Forms Sandeep Nema, John D. Ludwig, 2010-08-26 Pharmaceutical Dosage Forms Parenteral Medications explores the administration of medications through other than the enteral route First published in 1984 as two volumes and then last revised in 1993 this three volume set presents the plethora of changes in the science and considerable advances in the technology associated with these Pharmaceutical Dosage Forms Kenneth E. Avis, 2018-05-04 Completely updated and enlarged to three products volumes originally published as two volumes the Second Edition of Pharmaceutical Dosage Forms Parenteral Medications examines every important aspect of sterile drug products This volume 3 offers comprehensive coverage of medical devices quality assurance and regulatory issues This in depth reference and text discusses regulatory requirements in record keeping based on the US Food and Drug Administration's FDA Current Good Manufacturing Practices places special emphasis on methods of detecting counting and sizing particles offers new perspectives on contemporary validation concepts and how they affect the validation process explains current FDA enforcement activities the voluntary compliance policy select court cases and how these relate to parenterals provides recent materials on the use of audits as a means of verifying the efficacy of manufacturing control systems highlights new US regulations for medical devices and examines quality assurance including new information on biological control tests for medical device materials With the contributions of leading experts volume 3 of Pharmaceutical Dosage Forms Parenteral Medications is intended as a day to day reference for pharmacists medical device manufacturers quality control and regulatory personnel chemists and drug patent and litigation attorneys as well as a text for upper level undergraduate graduate and continuing education students in the pharmaceutical sciences

Pharmaceutical Manufacturing Handbook Shayne Cox Gad, 2008-03-11 With its coverage of Food and Drug Administration regulations international regulations good manufacturing practices and process analytical technology this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing

In addition the book discusses quality assurance and validation drug stability and contamination control all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing Pharmaceutics Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2022-09-07 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery It presents its subject following the principles of physical pharmacy product design and drug regulations This tripartite structure allows readers to move from theory to practice beginning from a firm foundation of physical pharmacy principles including drug solubility and stability estimation rheology and interfacial properties From there it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States European Union and Japan Readers of the second edition of Integrated Pharmaceutics will also find A glossary defining key terms extensive informative appendices and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded with additional new chapters including one entitled Biotechnology Products Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design design space analysis process analytical technology polymorphism characterization blend sample uniformity and stability protocols Integrated Pharmaceutics is a useful textbook for graduate students in pharmaceutical sciences drug formulation and design and biomedical engineering In addition professionals in the pharmaceutical industry including regulatory bodies will find it a helpful reference guide

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molecules are candidates for clinical trial investigation and subsequent commercialization a number of other activities must take place while research and development on these molecules continues The active ingredient itself must be formulated into a finished dosage form that can be conveniently used by health care professionals and patients Properties of the biopharmaceutical molecule must be clearly understood so that the appropriate finished product formulation can be developed Finished product formulation development includes not only the chemical formulation but also the packaging system the manufacturing process and appropriate control strategies to assure such good manufacturing practice attributes as safety identity strength purity and quality Water-Insoluble Drug Formulation Ron Liu, 2008-01-18 Scientists have attributed more than 40 percent of the failures in new drug development to poor biopharmaceutical properties particularly water insolubility Issues surrounding water insolubility can postpone or completely derail important new drug development Even much needed reformulation of currently marketed products can be significantly affected by these challenges Water Insolubility is the Primary Culprit in over 40% of New Drug Development Failures The most comprehensive resource on the topic this second edition of Water Insoluble Drug Formulation brings together a distinguished team of experts to provide the scientific background and step by step guidance needed to deal with solubility issues in drug development Twenty three chapters systematically describe solubility properties and their impact on formulation from theory to industrial practice With detailed discussion on how these properties contribute to solubilization and dissolution the text also features six brand new chapters on water insoluble drugs exploring regulatory aspects pharmacokinetic behavior early phase formulation strategies lipid based systems for oral delivery modified release of insoluble drugs and scalable manufacturing aspects The book includes more than 15 water insoluble drug delivery systems or technologies illustrated with case studies featuring oral and parenteral applications Highlighting the most current information and data available this seminal volume reflects the significant progress that has been made in nearly all aspects of this field Ocular Theraputics and Drug Delivery Indra K. Reddy, 1995-12-12 Since ocular therapeutics and drug delivery is a subject of interest to specialists from various disciplines such as chemical biochemical medical pharmaceutical and toxicological it truly presents a unique situation requiring a multi disciplinary approach in understanding and addressing various problems Yet we see that scientists associated with these areas are working by and large independently of one another thus limiting dissemination of knowledge experience and ideas that would greatly enhance the overall progress in this area of research Regrettably the information currently available in ocular therapeutics and drug delivery though extensive is still fragmented into various disciplines making meaningful synthesis difficult Several books are available that cover one or two aspects of the multi disciplinary fields on an individual basis however none is available that covers all of them The chapters contained in this book are specific to various interrelated areas of ocular therapeutics and drug delivery and are written by acknowledged experts from both academia and industry The book itself is divided into five parts namely I overview basic principles and methodology II

pathopharmacology and clinical applications III chemical biochemical approaches to ocular drug delivery IV formulation and drug delivery considerations and V industrial and regulatory considerations Individual chapters in each section apart from presenting a concise text entail an extensive listing of references Parenteral Medications, Fourth Edition Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration Key Features Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies The book is divided into seven sections Section 1 Parenteral Drug Administration and Delivery Devices Section 2 Formulation Design and Development Section 3 Specialized Drug Delivery Systems Section 4 Primary Packaging and Container Closure Integrity Section 5 Facility Design and Environmental Control Section 6 Sterilization and Pharmaceutical Formulation Pharmaceutical Processing Section 7 Quality Testing and Regulatory Requirements Development of Peptides and Proteins Lars Hoygaard, Sven Frokjaer, Marco van de Weert, 2012-11-14 The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products Pharmaceutical Formulation Development of Peptides and Proteins Second Edition discusses the development of therap **Pharmaceutical Dosage Forms** Herbert Lieberman, Martin Rieger, Gilbert S. Banker, 2020-08-26 Stressing the theory involved in formulating suspensions emulsions and colloidal drug products this Second Edition of a well received reference test highlights typical formulations the avoidance of formulation pitfalls and compliance with established regulatory principles The Future of Pharmaceutical Product Development and Research, 2020-08-19 The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences also highlighting key developments research and future opportunities Written by experts in the field this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development Each chapter covers fundamental principles advanced methodologies and technologies employed by pharmaceutical scientists researchers and the pharmaceutical industry The book focuses on excipients radiopharmaceuticals and how manufacturing

Sterilisation of Polymer Healthcare Products Wayne J. Rogers, 2005 Sterilisation has always been challenging but sterilisation of healthcare products and polymers especially together is an even greater challenge how do you sterilise without adversely affecting the end use or the end user This book discusses all the sterilisation methods used for polymeric healthcare products both traditional and new Aseptic Pharmaceutical Manufacturing II Michael J. Groves, Ram Murty, 2020-08-14 Asceptic Pharmaceutical Manufacturing II explores the sophisticated technology developments and applications that allow aseptic processing to approach the sterility levels achieved with terminal sterilization Written by experts in sterile manufacturing this book covers aseptic technology developments and applications and makes a valuable contribution to understanding the issues involved in aseptic manufacture Topics include the processing of biopharmaceuticals lyophilization personnel training radiopharmaceuticals hydrogen peroxide vapor sterilization regulatory requirements validation and quality systems Multiscale Technologies For Cryomedicine: Implementation From Nano To Macroscale John C Bischof, Shawn Xiaoming He, 2016-06-21 The use of micro nanotechnology in cell and tissue engineering and especially for cell and tissue preservation is at the peak of its activity now with scientific output expected to continue growing in the coming years Micro and nanotechnologies have induced paradigm shifts in many scientific fields and as featured in this edited volume they are having important impact in the field of cryomedicine The book gives an overview of the recent progress in implementing multiscale micro and nanoscale technologies to improve the outcome of various cryomedical applications including cryosurgery cryopreservation lyopreservation and to understand the fundamental engineering and science underpinning the applications This is the first book that will provide both an introductory and in depth account of applying the multiscale technologies in cryomedicine **Sterile Product Development Parag** Kolhe, Mrinal Shah, Nitin Rathore, 2013-10-12 This comprehensive book encompasses various facets of sterile product

development Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book Formulation approaches that discuss a variety of dosage forms including protein therapeutics lipid based controlled delivery systems PEGylated biotherapeutics nasal dosage form and vaccines Process container closure and delivery considerations including freeze thaw process challenges best practices for technology transfer to enable commercial product development innovations and advancement in aseptic fill finish operations approaches to manufacturing lyophilized parenteral products pen auto injector delivery devices and associated container closure integrity testing hurdles for sterile product closures Regulatory and quality aspects in the areas of particulate matter and appearance evaluation sterile filtration admixture compatibility considerations sterilization process considerations microbial contamination investigations and validation of rapid microbiological methods and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development

Chemical Engineering in the Pharmaceutical Industry Mary T. am Ende, David J. am Ende, 2019-04-08 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

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