

Aseptic Pharmaceutical Manufacturing II

APPLICATIONS FOR THE 1990s

Edited by Michael J. Groves and Hans Moritz

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SB Merriam

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Aseptic Pharmaceutical Manufacturing II Michael J. Groves, Ram Murty, 1995-05-31 Aseptic 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

Pharmaceutical Preformulation and Formulation Mark Gibson, 2016-04-19 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

Sterile Drug Products Michael J. Akers, 2016-04-19 Sterile Drug Products Formulation Packaging Manufacturing and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions suspensions ophthalmics and freeze dried products This Pharmaceutical Manufacturing Handbook Shayne Cox Gad, 2008-03-17 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

Freeze-Drying/Lyophilization Of Pharmaceutical & Biological Products, Revised and Expanded Louis Rey, Joan C. May, 2004-01-21 Thoroughly acquainting the reader with freeze drying fundamentals Freeze Drying Lyophilization of Pharmaceutical and Biological Products Second Edition carves practical guidelines from the very latest theoretical research technologies and industrial procedures It delineates the best execution of steps from closure preparation and regulatory control of products to equipment sterilization and process validation With 13 new chapters providing state of the art information the book unveils innovations currently advancing the field including LYOGUARD

packaging for bulk freeze drying and the irradiation of pharmaceutical and biological products **Pharmaceutical Manufacturing Formulations** Dr. Priyanka Gupta Manglik, 2024-08-15 This book provides detailed insight into the various aspects of pharmaceutical manufacturing covering formulations process design technology and regulatory requirements essential for professionals in the pharma industry **Human Factors in Organizational Design and Management-VI** P. Vink, E.A.P. Koningsveld, S. Dhondt, 1998-08-14 This book contains a series of papers that were presented during the Sixth IEA International Symposium on Human Factors in Organizational Design and Management ODAM 98 The Symposium was sponsored jointly by the International Ergonomics Society the Dutch Ergonomics Society NIA TNO and The Ministry of Social Affairs and Employment These experiences include new ideas research results tools and applications of human organization interface technology to improving work systems New technology changing work force demographics changing attitudes and values about work and what constitutes real quality of work life have heightened the need for a true systems approach to optimizing the interfaces between humans technology and organizational structures and processes Growing world competition and the related need to make organizations more productive and efficient have further intensified this need to improve work systems This need is reflected in the rapid development of macroergonomics methods and applications since the first of these ODAM Symposia in 1984 What then was recognized by only a few researchers and practitioners has now become a widely accepted part of the human factors ergonomics discipline As demonstrated by the papers contained herein application of macroergonomics is having a very real positive impact on sociotechnical systems internationally Included in this volume are a broad selection of papers on theory methodology tools research findings and case studies from leading professionals throughout the world This volume thus provides the reader with some of the latest developments in human organization interface technology Collectively these papers should provide the reader with a good conceptual understanding of the ergonomic approach to work system design and of its tremendous potential for improving work systems and the human condition in all cultures Validation of Pharmaceutical Processes James P. Agalloco, Frederick J. Carleton, 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive The many chapters added to the prior compilation examine va **Handbook of Pharmaceutical Manufacturing Formulations** Safaraz K. Niazi, 2016-04-19 No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products for obvious reasons With the increasing number of potent products particularly the new line of small protein products joining the long list of proven sterile products the technology of manufacturing ster *Biopharmaceuticals* Gary Walsh, 1998-06-18 Biopharmaceuticals Biochemistry and Biotechnology provides a comprehensive and up to date overview of the science and medical applications of biopharmaceutical products Specific chapters detail therapeutic substances such as interferons

interleukins and growth factors as well as hormones therapeutic enzymes blood products antibodies and vaccines While the emphasis is placed upon polypeptide based therapeutic agents the potential applications of nucleic acids with regard to gene therapy and antisense technology are considered in the final chapter In addition other chapters detail regulatory issues as applied to biopharmaceuticals and how such products are manufactured in practice The author has produced an up to date easy to read book and each chapter is supplemented with a substantial further reading section It is of particular relevance to students undertaking advanced undergraduate or postgraduate courses in biotechnology biochemistry pharmaceutical science or medicine Its scope also renders it an ideal reference for those already employed in the bio pharmaceutical sector who wish to gain a better overview of the industry in which they work

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