

Sterile Pharmaceutical Manufacturing: Applications for the 1990's: 002

Olson, Wayne P.

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Sterile Pharmaceutical Manufacturing Applications For The 1990s Volume 2

**Michael K. Akers, Michael K.
Larrimore, Dana Guazzo**



Sterile Pharmaceutical Manufacturing Applications For The 1990s Volume 2:

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 *Aseptic Pharmaceutical Manufacturing II* Michael J. Groves, Ram Murty, 1995-05-31 *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 *Parenteral Quality Control* Michael K. Akers, Michael K. Larrimore, Dana Guazzo, 2002-11-20 Providing a well written and easy to read review of the subject this reference describes the most recent breakthroughs in the validation and execution of testing schemes for parenteral quality control Emphasize testing methodologies for the evaluation of package integrity finished product contamination and sterility the book is a guide to test

Animal Cell Culture and Production of Biologicals Ryuzo Sasaki, Kouji Ikura, 2012-12-06 In the past two decades the importance of animal cell technology has increased enormously First useful proteins can be produced by cultured animal cells in which the desired product can be modified and organized so as to retain its biological function Second studies of cultured cells can provide information needed to understand molecular mechanisms that govern what happens in tissues organs and even entire organisms For this second purpose biochemists and molecular biologists may need a large number of such cells Third cultured cells can be used instead of tissues and organs clinically The Third Annual Meeting of the Japanese Association for Animal Cell Technology JAACT at which participants from abroad were warmly welcomed was held in Kyoto on December 11 13 1990 It was organized around the idea of providing a place for the review of much new data on such applications of cultured cells and for exchanges of the views of the participants about progress in the field This volume divided into seven sections contains the proceedings of the meeting The first section reviews the molecular basis of the control of animal cell growth In the following sections physicochemical and biochemical factors for cell growth and production of biologicals cell culture systems including serum free culture new cell lines specific products and their characteristics and in vitro assays for toxic carcinogenic and pharmacological effects are taken up in their turn

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

Control of Particulate Matter

Contamination in Healthcare Manufacturing Thomas A. Barber,1999-10-31 This book offers practical applications addressing the specifics of contamination including particle origination characterization identification and elimination with a special focus on quality considerations Written by an industry expert this material offers a clear and concise understanding of particle populations and their control in stability efficacy and predictability in the manufacture of healthcare products Complete with a full color insert of micrographs illustrating commonly encountered particulate matter and over eighty figures tables and charts Features

Handbook of Nonmedical Applications of Liposomes Yechezkel

Barenholz,2018-01-31 Liposomes have become an important model in fundamental biomembrane research including biophysical biochemical and cell biological studies of membranes and cell function They are thoroughly studied in several applications such as drug delivery systems in medical applications and as controlled release systems microencapsulating media signal carriers support matrices and solubilizers in other applications While medical applications have been extensively reviewed in recent literature there is a need for easily accessible information on applications for liposomes beyond pharmacology and medicine The Handbook of Nonmedical Applications of Liposomes fills this void This unique new handbook series presents recent developments in the use of liposomes in many scientific disciplines from studies on the origin of life protein function and vesicle shapes to applications in cosmetics diagnostics ecology bioreclamation and the food industry In these volumes many of the top experts contribute extensive reviews of their work

Development and Manufacture of Protein Pharmaceuticals

Steve L. Nail,Michael J. Akers,2012-12-06 In this era of biotechnology there have been many books covering the fundamentals of recombinant DNA technology and protein chemistry However not many sources are available for the pharmaceutical development scientist and other personnel responsible for the commercialization of the finished dosage forms of these new biopharmaceuticals and other products from biotechnology This text will help to fill this gap Once active biopharmaceutical 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 **Pharmaceutical**
Biotechnology Melvin E. Klegerman,1992 Current Catalog National Library of Medicine (U.S.),1993 First multi year
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