

# Parenteral Quality Control

## Sterility, Pyrogen, Particulate, and Package Integrity Testing

### Third Edition, Revised and Expanded



Michael J. Akers  
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# Parenteral Quality Control Sterility Pyrogen Particulate And Package Integrity Testing

**Wei Wang, Christopher J. Roberts**



## **Parenteral Quality Control Sterility Pyrogen Particulate And Package Integrity Testing:**

*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

**Parenteral Quality Control** Michael J. Akers, 1993 **Parenteral Quality Control** Michael J. Akers, 1985 Parenteral Quality Control Michael J. Akers, 1985

**Aggregation of Therapeutic Proteins** Wei Wang, Christopher J. Roberts, 2010-12-28 This book gives pharmaceutical scientists an up to date resource on protein aggregation and its consequences and available methods to control or slow down the aggregation process While significant progress has been made in the past decade the current understanding of protein aggregation and its consequences is still immature Prevention or even moderate inhibition of protein aggregation has been mostly experimental The knowledge in this book can greatly help pharmaceutical scientists in the development of therapeutic proteins and also instigate further scientific investigations in this area This book fills such a need by providing an overview on the causes consequences characterization and control of the aggregation of therapeutic proteins

**Pharmaceutical Process Validation** Robert A. Nash, Alfred H. Wachter, 2003-03-27 The third edition of this text contains additional chapters which cover troubleshooting procedures validation in contract manufacturing and current harmonization trends

*Heat Sealing in Packaging* Abdellah Aji, Ebrahim Jalali Dil, Amir Saffar, Zahra Kanani Aghkand, 2023-05-22 The book explains concept and principle of heat sealing and the correlation between molecular properties and seal performance First theoretical aspects of heat sealing and the mechanism involved in seal formation are discussed Then different test methods for evaluating seal and hot tack performance and quality are reviewed Different common sealant materials in flexible packaging are discussed including multiphase and bioplastic sealants Effect of processing condition and material characteristics on seal and hot tack performance of sealant materials are reviewed Mathematical models are presented as powerful tools to optimize sealing condition in order to balance production cost and seal properties Finally practical examples of sealant design are introduced in food and industrial packaging

Analysis of Aggregates and Particles in Protein Pharmaceuticals Hanns-Christian Mahler, Wim Jiskoot, 2012-01-24 This book describes how to address the analysis of aggregates and particles in protein pharmaceuticals provides a comprehensive overview of current methods and integrated approaches used to quantify and characterize aggregates and particles and discusses regulatory requirements Analytical methods covered in the book include separation light scattering microscopy and spectroscopy

Nanoparticulate Drug Delivery Systems Deepak Thassu, Michel Deleers, Yashwant Vishnupant Pathak, 2007-03-30 With the advent of analytical techniques and capabilities to measure particle sizes in nanometer ranges there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery Nanoparticulate Drug Delivery Systems addresses the scientific

methodologies formulation processing applications recent trends and e Quality Control Carol Krismann,1990 The Effect of Pressure Differential on Microbial Penetration of a Sterile Medical Device Tray Jane Erin Severin,2006

**Handbook of Modern Pharmaceutical Analysis** Satinder Ahuja,Stephen Scypinski,2001-08-02 This book describes the role modern pharmaceutical analysis plays in the development of new drugs Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug Coverage includes state of the art topics such as analytics for combinatorial chemistry and high throughput screening formulation development stability studies international regulatory aspects and documentation and future technologies that are likely to impact the field Emphasis is placed on current easy to follow methods that readers can apply in their laboratories No book has effectively replaced the very popular text *Pharmaceutical Analysis* that was edited in the 1960s by Tak Higuchi This book will fill that gap with an up to date treatment that is both handy and authoritative *Pyrogens* Frederick C. Pearson,Marlys Weary,James H. Jorgensen,1985 *Handbook of Institutional Pharmacy Practice* ,1992 **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 book is based on the courses he has delivered for over three decades to over 3000 participants and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common This is an ideal reference book for those working directly and indirectly with sterile dosage forms be it product development formulation package process analytical manufacturing quality control quality assurance regulatory purchasing or project management This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools providing basic knowledge and principles in four main areas of parenteral science and technology Product development including formulation packaging and process development Manufacturing including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control Quality and regulatory including the application of good manufacturing practice regulations aseptic processing guidelines and unique quality control testing methods for the sterile dosage form Clinical aspects including administration potential hazards and biopharmaceutics of sterile products in a clinical setting **Polish Journal of Pharmacology and Pharmacy** ,1986 **Pharmaceutical Practice** Arthur J. Winfield,R. Michael E. Richards,1998 Pharmacists have a fundamental professional duty to provide the highest standards of pharmaceutical care for patients and clients Patient interaction is an expanding role for pharmacists whether in hospital or community This new edition of *Pharmaceutical Practice* provides the core knowledge and skills pharmacy students and practitioners need to allow them to take on this key responsibility It covers the important areas of interaction and communication teamwork and cost effective management as

well as core scientific information on pharmaceutical products and appliances everything from prescriptions and routes of administration to intravenous additives parenteral nutrition and dialysis Several totally new chapters have been added on the following topics the essential medicines concept pharmacy management complementary and alternative medicines pharmacoeconomics and presentation skills There has been major expansion of many chapters including social and behavioural aspects of pharmacy calculations medicines information and drug administration by the inhaled route And all other chapters have been thoroughly revised and updated Throughout the book the Editors aim for this edition as for the last remains constant to invite chapter authors who are experts in their fields and to oversee the entire book to make it a coherent and comprehensive whole thereby providing a sound knowledge base for all aspects of good pharmacy practice

Book jacket     **Pharmaceutical Particulate Matter** Thomas A. Barber,1993     **Endotoxins** Kevin L. Williams,2007-02-23

This source expertly examines the discovery biological structure control and continued clarification of endotoxin from a parenteral manufacturing perspective with in depth discussion of state of the art technologies involving Limulus ameocyte lysate LAL such as assay development automation depyrogenation Completely revised and expanded this Third Edition contains the knowledge necessary to apply endotoxin testing in the increasingly complex pharmaceutical environment featuring sections detailing the latest information regarding clinical advances regulation standards and validation procedures for computerized kinetic tests     **Dose Optimization in Drug Development** Rajesh Krishna,2006-05 This reference provides a concise overview of the key principles in dose selection and optimization and demonstrates applicability to recent successful new drug applications Compiling key issues and current research on safety efficacy and clinical pharmacology and PK PD this volume critically highlights the multidisciplinary nature of drug development and spans the fields of pharmacokinetics clinical pharmacology biostatistics and experimental medicine

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