

# Parenteral Quality Control

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

### Third Edition, Revised and Expanded



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# Parenteral Quality Control Sterility Pyrogen Particulate And Package Integrity Testing

**Michael J. Akers**



## **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, Dana Morton Guazzo, 1994

**Heat Sealing in Packaging** Abdellah Ajji, 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 fl exible 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

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

*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 Quality Control Carol Krismann,1990

**Nutrition and Integrative Medicine** Aruna Bakhru,2018-08-06 While medical professionals continue to practice traditional allopathic medicine the public has turned toward nutritional and integrative medical therapies especially for addressing the proliferation of chronic diseases Written by leaders in the academic and scientific world Nutrition and Integrative Medicine A Primer for Clinicians presents various modalities to help restore health This book provides users with a guide to evaluating and recommending nutritional and integrative therapies The book offers insights on the microbiome of the human body examines the relationship of human health to the microbiome of the food we ingest and introduces the concept of food as information It provides enlightenment on anti aging and healing modalities mind body medicine and an investigation of psychological trauma as related to disease causation Integrative therapies including water light and sound therapy are explored and information on healing chronic disease through nutrition the tooth body connection the role of toxins in disease causation and electromagnetic field hypersensitivity as well as its management is presented **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

**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

Pyrogens Frederick C. Pearson, Marlys Weary, James H. Jorgensen, 1985 *The Effect of Pressure Differential on Microbial Penetration of a Sterile Medical Device Tray* Jane Erin Severin, 2006 **Handbook of Institutional Pharmacy Practice**, 1992 *Pharmaceutical Particulate Matter* Thomas A. Barber, 1993 **Polish Journal of Pharmacology and Pharmacy**, 1986 *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 amoebocyte 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 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

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