

Book reviews

Sterilization of Drugs and Devices: Technologies for the 21st Century

Fred M. Nordhauser, Wayne P. Olson (Editors), Interpharm Press, Buffalo Grove, IL, USA, 1998. 554 pp., ISBN: 1-57491-060-4

The book deals with the terminal sterilization and the aseptic processing of pharmaceutical products. Since parenteral drug delivery systems have to meet the pharmacopoeial requirements of sterility, these topics are an important area of research. The book is divided into 14 chapters and discusses currently available sterilization techniques such as moist heat or γ -irradiation, but novel methods are also introduced in detail. For example, sterilization using pulsed white light and low temperature plasmas are presented in full. As a number of drugs and pharmaceutical application devices are thermally liable, these developments represent important and useful alternatives for the design of novel sterile manufacturing processes.

Other stimulating chapters cover filter sterilization of drug solutions, chemical decontamination of surfaces, viral inactivation and removal and isolated aseptic filling lines. Moreover, interesting approaches concerning the steam sterilization-in-place are presented in detail. Both the mechanistic principles of the techniques and the mechanisms of killing and inactivation of microorganisms are presented. Concerning the suitability of the techniques described, most of the chapters also discuss the pros and cons of the methods described.

Beside sterilization techniques, a number of methods used for sterility testing are described extensively, giving a helpful overview for the interested reader.

The book ends with an overview on the parametric release of drug products, dealing with the submissions approved by the U.S. Food and Drug Administration (FDA). Process validation studies, effective control, monitoring and documentation of the sterilization process allowing the product release without performing sterility tests are discussed.

Since the chapters of this 'Handbook' of the sterilization of drugs and devices are written by different authors, some aspects are discussed from several points of view. There-

fore, with this book both readers who only tend to learn about the sterilization techniques but also potential designers of new sterile manufacturing processes will have a helpful manuscript. Especially the chapters dealing with the sterilization of pharmaceutical solutions, the terminal γ -irradiation and the sterilization with low temperature plasmas are interesting sources for readers who want to have a detailed description of the processes and mechanisms of sterilization. Other chapters such as the SIP (sterilization-in-place) and the in-line sterilization of liquids discussing the technical equipment for the sterilization procedure in detail are a useful tool for potential manufacturers of sterile products.

From a microbiological point of view, the book is also very interesting. Several chapters intensively focus on the mechanism of viral and bacterial inactivation. Especially chapter 2 which discusses the killing and inactivation processes of microorganisms. In this context, the behavior of bacterial populations, the formation of endospores, and the killing process are in the center of interest of this chapter. Moreover, this to my mind, very important chapter describes the microbiological effects of the sterilization and filtration processes presented in the following chapters.

Altogether the book takes an excellent and useful approach. The chapters contain detailed guides to well established and novel sterilization techniques, aseptic processing and sterility testing. Consequently, I strongly recommend the book to everyone who is interested in the sterilization of drugs. Furthermore, since it clearly describes the different topics, the book is also well suited as an overview for students of medicine, biology and pharmaceutics.

Professor Dr. Thomas Kissel
Department of Pharmaceutics and Biopharmacy
Philipps-Universität Marburg
Ketzerbach 63, 35032 Marburg
Germany

PII: S0939-6411(98)00063-0
