



Book review

Parenteral Quality Control Sterility, Pyrogen, Particulate, and Package Integrity Testing, Third Edition, Revised and Expanded

Michael J. Akers, Daniel S. Larrimore, Dana Morton Guazzo (Eds.), *Drugs and the Pharmaceutical Sciences*, Volume 125, Marcel Dekker, New York, 2003, ISBN: 0-8247-0885-7

Parenteral products present three unique analytical challenges namely sterility, apyrogenicity and freedom from particulate contamination. A further part analytical and part design feature is that product packaging must maintain the former three requirements throughout a product's proposed shelf-life. The title therefore completely encapsulates the contents of the book's four chapters. Predictably, the sterility text consumes around one third of the book and provides a very comprehensive summary of the development and application of this test. Information is provided on the statistics (tabular information may have been better than graphs), media and environmental requirements with the latter also covering the move to testing inside isolators. Pyrogen testing provides a thorough examination of the two major assay methods dealing mainly with Limulus based methods, which are supplanting the rabbit test. The chapter dealing with particulate

contamination discusses this problem from the aspect of source of contamination and methods for detection and enumeration. Although it is interesting to note that only a couple of references (with the exception of books and pharmacopoeias) are later than the 1990's, possibly indicating that this particular quality parameter is well handled by the pharmaceutical industry. The final chapter deals with the integrity testing of container closures and covers development testing through to production testing, successfully linking the two. The book provides a review of the four idiosyncratic analytical procedures applied to parenteral products. However, the emphasis is on American based standards, which is slightly limiting. Overall the content will serve as a very useful reference to those already working in the field and a comprehensive introduction to those entering the field.

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