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BOOKS

REVIEWS

Quality Control in the Pharmaceutical Industry, Vol. 2. Edited by M. S. COOPER. Academic, 111 Fifth Ave., New York, NY 10003, 1973. 332 pp. 15.5 × 23.5 cm. Price $22.00.

This volume is composed of six chapters covering quality control of aerosol products and veterinary biologicals, the quality control test program of the National Center for Drug Analysis for drug products, pyrogen testing, stability, and sterilization. As in any multiauthor book, certain chapters stand out in comparison with others.

The chapter on Pyrogen Testing of Parenteral Pharmaceuticals by G. R. Personeus provides an excellent comprehensive in-depth discussion of the variables that can influence pyrogen test results and provides the scientist concerned or interested in pyrogen testing with information of how to best use this test. This chapter best fulfills the aim of the editor of the book in dealing in depth with a distinct aspect of the subject of quality control of pharmaceuticals.

The chapter on Pharmaceutical Product Stability by C. J. Lintner provides a general condensed review on stability of pharmaceuticals. Information is provided in this chapter on regulations applicable to stability, types of degradation (hydrolysis, oxidation–reduction, *etc.*,) physical stability of different dosage forms, preservatives, antioxidants, chelating agents, isothermal *versus* nonisothermal reactions, containers and closures, and computer programs for treating and storing stability data; there are also short synopses on stability attributes of specific drug compounds. Because of the considerable amount of information the author provides, no one area of his presentation could be given in depth. The author of this chapter has provided an excellent comprehensive bibliography on his subject.

The chapter on Quality Control of Veterinary Biologics by G. R. Sharpless is concerned for the most part with potency testing of bacterial, viral, sera, toxoid and bacterin–toxoid, and diagnostic products. It also provides a brief review of the tests and procedures outlined by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, Veterinary Services Branch, which is responsible for the government regulation of veterinary biologics.

The chapter on the Control of Sterilization Procedures by R. R. Ernst does not discuss sterility tests or testing methods, but instead gives an in-depth presentation of the various factors involved in steam and gaseous sterilization and the types of equipment utilizing these two methods of sterilization. Sterilization by radiation, filtration, and dry heat is treated superficially.

The chapter on Quality Control for Pharmaceutical and Cosmetic Aerosol Products by J. J. Sciarra has only a minor portion related to the quality control of aerosol products and components. The major portion of the chapter is concerned with the general philosophy and principles of quality control and assurance in the pharmaceutical industry.

The chapter on The Test Program of the National Center for Drug Analysis on the Quality Control of Drug Products by A. W. Steers discusses the FDA regulations pertaining to drug quality, the organization of the National Center for Drug Analysis (NCDA), the Retail-Based Drug Monitoring Program, and the Formulator-Oriented Rx Drug Studies (FORDS) Program. Data are presented on the drug products evaluated from the retail-based and formulator-based studies at the NCDA.

Certain chapters of this volume provide the pharmaceutical scientist, quality control chemist, and biologist with pertinent information not readily found in other books which should be of use in their daily work.

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Analytical Profiles of Drug Substances, Vol. 4. Edited by KLAUS FLOREY. Academic, 111 Fifth Ave., New York, NY 10003, 1975. 16 × 23.5 cm. 526 pp. Price $26.50.

Volume 4 of this unique series provides coverage of 20 additional drugs including cefazolin, estradiol valerate, methaqualone, norethindrone, and tybamate. Utilizing a monograph format, these volumes provide frequently difficult to locate information on physical and chemical data, methods of synthesis, pathways of physical and biological degradation, metabolism, and methods of analysis.

Each monograph is amply illustrated and well referenced. Considerable information concerning the drugs is compiled and presented in an easy-to-use format. These volumes should be available to everyone working in pharmaceutical research.

Staff Review