REVIEWS

Essentials of Drug Product Quality: Concepts and Methodology. By MAHMOUD M. ABDEL-MONEM and JAMES G. HENKEL. C. V. Mosby, 11830 Westline Industrial Drive, St. Louis, MO 63141. 1978. 274 pp. 20 × 25 cm. Price $14.95.

This text, according to the preface, is designed for first professional year pharmacy students. It is unique in two respects: (*a*) it attempts to integrate the elements of quality assurance of drugs and drug products with the accompanying methodology (directed toward both the drug product and the drug in biological fluid); and (*b*) it employs a format and style designed to support the use of the personalized system of instruction (PSI). PSI is described as "characterized by a mastery learning requirement, student self-pacing within the course, the use of proctors for immediate grading of tests taken by students for each unit (chapter), and infrequent lectures." Nevertheless, the format should lend itself well to a more traditional mode of instruction. In this regard, each of the 21 chapters begins with a list of performance objectives for the student and closes with a more than ample list of study questions and practice problems. The writing generally is very readable and lucid.

The first three chapters provide a well-planned, coherent treatment of the principles of drug product selection and include an introduction to dosage forms, the history and purpose of the official compendia, the role played by the FDA in drug product quality assurance, and drug product selection based on pharmaceutical equivalence and bioequivalence. However, some instructors may desire more depth in the treatment of dosage forms and bioequivalence. The treatment of the basis, application, and interpretation of official tests for unit-to-unit variation and uniformity (Chapter 2) is especially well done. However, the few sentences devoted to the dissolution test in Chapter 3 are incomplete and superficial. Chapters 4 and 5, which discuss data analysis and significance testing, are especially noteworthy.

The preface suggests that the analytical methodology chosen to be discussed (Chapters 6–20) is that supporting the quality assurance of drugs and states that the "important analytical methods" are covered. This philosophy apparently influenced the selection of topics, which include ionic equilibria (K_{sp} and acid–base chemistry) (two chapters), solvent extraction principles (one chapter), gravimetric analysis (one chapter), volumetric analysis (acid–base and redox) (two chapters), spectrometry (UV, colorimetry, IR, fluorescence, and mass spectrometry) (five chapters), chromatography (column, TLC, GLC, and HPLC) (three chapters), and radioactivity (one chapter). The emphasis is on the analysis of organic drugs and less on inorganic substances, as evidenced by the absence of precipitation and complexometric titrations among the volumetric techniques discussed and the omission of the analysis of heavy-metal ions among the gravimetric techniques. Also, electrochemical techniques are ignored, although cursory consideration is given to redox potentials in the section on redox titrations and potentiometric end-point determination is referred to in some examples of titrimetric analysis.

Each subject begins with a review of chemical principles at an elementary, general chemistry level. However, the scope often is limited. For example, amphiprotic salts and polyprotic acids are not dealt with in the chapter on acid–base equilibria, the use of acid–base titrimetry in the analysis of esters by saponification is discussed but a related application to the acylation of alcohols is not, and although chemically bonded stationary phases in HPLC are considered, formal allusion to reversed-phase methodology, one of the fastest growing techniques applied to drug analysis, is absent. However, the chapters on spectrometric and chromatographic methods are particularly well presented and provide the best depth of coverage of any of the topics discussed.

Among the most useful components of the chapters on methodology are the examples given to illustrate the principles. These examples, taken primarily from USP XIX and NF XIV, form an essential part of the textual material of the chapter since, in many cases, information or methodology may be presented here that is not dealt with in the main part of the chapter. Similar examples from the compendia also are offered as problems in the study guide found at the end of each chapter.

Chapter 21 deals with the use of the scientific literature and is followed by an appendix reviewing elementary mathematical operations (significant figures, exponents, powers, roots, and logarithms).

In summary, this is a generally well-written and well-designed text that uniquely incorporates principles of drug product selection, quality assurance, and analytical methodology. As such, the text could find application in a modern pharmacy curriculum; however, supplementation may be needed in certain areas. The major portion of the text provides a survey at the elementary level of certain methodology applied to the analysis of organic drugs. For more detailed and more comprehensive coverage of these topics, one of the more standard texts in pharmaceutical or analytical chemistry may be more appropriate.

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The Basis of Medicinal Chemistry: Burger's Medicinal Chemistry, 4th Ed., Part I. Edited by MANFRED E. WOLFF. Wiley, 605 Third Ave., New York, NY 10016. 1980. 497 pp. 17 × 25 cm. Price $29.50.

Part I is the first of a three-volume work containing 12 chapters. This multiauthored text presents underlying principles of medicinal chemistry and includes new areas and topics representing the changes in the pharmaceutical sciences since the last edition. The authors, chosen by the editor, are considered to be authorities in their field. The topics are reminiscent of those in the "Principles of Drug Action: The Basis of Pharmacology, 2nd ed.," by A. Goldstein, L. Aronow, and S. M. Kalman.

The 12 subjects covering 478 pages in this volume were selected apparently on the basis of their broad appeal. They include an introductory chapter dealing with a historical account of medicinal chemistry; one chapter on Drug Absorption, Distribution, and Elimination; two chapters on metabolism, Drug Biotransformation—Oxidation, Reduction, Hydrolytic and Conjugation Reactions and Chemical and Biological Factors Influencing Drug Biotransformation; three chapters based on drug–receptor interactions, Receptor Theories and Dose–Response Relationships, Drug–Receptor Geometry, and The Nature of the Drug–Receptor Bond; three chapters on the methods of drug design, Guidelines for Drug and Analog Design, Approaches to the Rational Design of Enzyme Inhibitors, and QSAR; and two chapters covering Drug Allergy and Chemical Carcinogenesis. The chapters on metabolism, drug–receptor interactions, and drug design were particularly interesting.

With well-written chapters, a thorough and updated literature coverage in most chapters (3451 references of which 1337 are in the introductory chapter) for further investigation, and a comprehensive subject index, this book accomplishes its purpose as a secondary source for the biologist and medicinal chemist in industry and academia. This text can be recommended as a useful reference to graduate students for an advanced course in medicinal chemistry and other disciplines (biochemistry, pharmacology, biophysics, microbiology, and bio-organic). Most researchers in these areas will find this book to be a useful addition to their library.

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Handbook of Basic Pharmacokinetics, 2nd ed. By WOLFGANG A. RITSCHEL. Drug Intelligence Publications, Hamilton, IL 62341. 1980. 454 pp. 11 × 19 cm. Price $19.50.

The author views this book not as a textbook but rather as a collection of pharmacokinetic facts. The book meets this definition well. It is a comprehensive collection of important facts necessary to the understanding of pharmacokinetics.

This edition has new sections on dosage adjustment in the elderly and