Book Reviews

Pharmacokinetic Analysis: A Practical Approach. Peter I. D. Lee and Gordon L. Amidon. Technomic Publishing Company, Inc., 851 New Holland Ave., Box 3535, Lancaster, Pennsylvania 17604. 1996. xiii, 548 pp., illustrations. $159.

The book "Pharmacokinetic Analysis, a Practical Approach" represents a novel approach to pharmacokinetic data interpretation that is robust in concept, universal in application, and relatively simple to use. The authors have reviewed a considerable spectrum of pharmacokinetic models and situations and described their interpretations in terms of a time constant approach, which they have selected as a unifying view for all areas of application.

The constants are defined as the times associated with individual pharmacokinetic processes involved in drug disposition. These contrast with such standard parameters as C_{max}, T_{max}, and AUC which are direct observations of drug concentration-time profiles. The time constant of any process is defined as the average time it would take for a process to move the equivalent of the total amount of drug from one pharmacokinetic compartment to another. By this method pharmacokinetics may be viewed as a number of processes that move drugs between places, each occurring in a characteristic length of time. It is claimed that this approach provides the pharmacokinetics novice with an intuitive view of the subject in allowing one to get a "feel" for the data and readily relate it to other data. The time constant approach also provides a "sensible" unit that is readily grasped. For specialists in the field, this approach provides a new way of looking at data, based on areas under drug-concentration-time profiles and area moment values.

The book is organized into five sections. The first section, consisting of four chapters provides a general introduction, physiological meaning, methods to calculate time constants, and applications to pharmacokinetic situations. The remaining four sections, consisting of fifteen chapters, describe the application of the time constant approach in four areas: influence of formulation on drug absorption; basic processes of absorption, distribution, metabolism, and excretion; concurrent medication and food effects; and special populations.

The book contains many literature references and has three appendices which describe the derivation of areas and areas under moment curves and evaluation of mean residence times. Software in the form of an Excel® macro spreadsheet for Windows® will be available to assist with developing and understanding examples given in the book.

In summary, this book takes a refreshing "new look" at pharmacokinetics analysis. It is provocative in providing a new yet relatively simple perspective, while it is realistic in that the time constant approach is largely independent of model complexity. The book is easy to read and should be useful for those entering or specializing in the area of pharmacokinetics.

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Handbook of Pharmacokinetic/Pharmacodynamic Correlation. Hartmut Derendorf and Günther Hochhaus, Eds. CRC Press, Inc., 2000 Corporate Blvd., N.W., Boca Raton, Florida 33431. 1995. viii, 483 pp., illustrations. $140.

The Handbook of Pharmacokinetic/Pharmacodynamic Correlation is a multi-authored compilation of topics addressing theoretical and practical aspects of the relationships between systemic levels of therapeutic agents and observed therapeutic or pharmacologic events.

In constructing the book, the editors have drawn from their own considerable experience and also that of a large number of contributors who are active in their areas of research. The first four chapters in the book are devoted to general principles of pharmacokinetic/pharmacodynamic (PK/PD) modeling. These include modeling with reversible and irreversible pharmacologic effects, the use of modeling in drug development and also dose optimization. The remaining thirteen chapters describe current research on PK/PD relationships for a variety of therapeutic drug classes including cardiovascular agents, central nervous system drugs, anesthetic agents, anticoagulants, antihistamines, corticosteroids, antibiotics and anticancer drugs. The book concludes with a chapter on computer applications in clinical pharmacokinetics and pharmacodynamics. Although there is appropriate emphasis on PK/PD modeling in the early sections of the book, examples of modeling are appropriately distributed throughout the remainder of the text, relevant to particular drug classes and therapeutic areas.

The editors have thus produced an excellent summary of current information that has been obtained using state of the art methodology across a broad spectrum of therapeutic areas. It is particularly noteworthy that, almost without exception, contributing authors have not only commented on difficulties associated with establishing predictable PK/PD relationships, but have also presented one or more approaches to resolve these difficulties. The use of surrogate markers in the case of some centrally active drugs is representative.

Overall, this is an excellent book that provides a wealth of information on the theory, practice and application of PK/PD relationships, in both preclinical and clinical environments. It would be a useful text for both undergraduate and graduate teaching, and is a must for any organization concerned with pharmacokinetics, pharmacology, and drug concentration-effect relationships, in drug-development or in clinical medicine. I look forward to reading the next book in this series as research in this challenging but critically important area continues.

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Principles of Pharmacology: Basic Concepts & Clinical Applications. Paul L. Munson, Editor-in-Chief, Robert A. Mueller, and George R. Breese, Eds. International Thomson

0724-8741/97/0200-0254$12.50/0

Publishing, 7625 Empire Drive, Florence, Kentucky 41042. 1996. xxvi, 1796 pp., illustrations. $89.95.

This voluminous tome is promoted by the editors as a reference book as opposed to a text. This is entirely correct. While it could be used for teaching purposes, its sections are much more useful as extensive sources of information related to various drug classes. The editor-in-chief and associate editors-in-chief have assembled an excellent selection of section editors who in turn have solicited chapters from knowledgeable scientists. The book flows very well for one written by so many individuals. It has a true international flavor.

The book is encyclopedic with 121 chapters organized into 15 sections plus a few additional chapters. The first section presents the usual general principles of pharmacology. The second (8 chapters) and third (11 chapters) sections are on peripheral and central neuropharmacology. The next sections cover cardiovascular and pulmonary pharmacology, renal pharmacology, and pharmacology of hormones and reproduction. Interestingly, there is an extensive section on the pharmacology of nutrients and nutritional diseases followed by sections on drugs affecting gastrointestinal function and drugs affecting blood, the immune system, and inflammation. Section X is on the pharmacology of the skin and is much more thorough than is usually found in pharmacology texts, encompassing 14 chapters. This is followed by sections on chemotherapeutic drugs, natural medicinal products and elements of toxicology. The final sections deal with governmental regulation of drugs (drug laws) and the pharmacology associated with special patient populations (critical care patients, those with AIDS, geriatrics, and Alzheimer's patients). Additional chapters are included on prescription writing and scientific responsibility. The latter is an interesting and timely addition.

The approach taken is that of a true pharmacology book. There is a heavy emphasis on the mechanisms of how drugs act to produce their effects. This is supported by a large number of very clear and illustrative drawings of physiological, biochemical and molecular biology pathways and interactions. The amount of information on therapeutic applications varies widely from chapter to chapter but is generally adequate. There is not much information, however, on the metabolism of these drugs although a cursory discussion of pharmacokinetics is usually included.

The book is as up to date as can be expected with a large, multi-authored text, although it is not clear what a "revised reprint" is compared to a new edition. It has a number of interesting features. Besides being very well illustrated, each chapter contains a large number of reviews which can be consulted for additional information without going back to an overwhelming number of original papers. Most of the book is easy to read with two large columns of print. An exception is when fine point is used which is very difficult to read. It should be noted that this book is also being advertised in a CD-ROM version. In either case, this is a useful reference tool.

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Microparticulate Systems for the Delivery of Proteins and Vaccines. Smadar Cohen and Howard Bernstein, Eds. Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016. 1996. ix, 525 pp., illustrations. $165.

Even thirty years ago it was impossible to accurately predict the revolution in microparticulate delivery systems we have today. Indeed, anyone who attempted future insight into the routine use of liposomes, PLGA, polyacrylates, self-adjuvanting polymers, polyphosphazines and the like would have been labeled a dreamer at best. And yet the future is upon us, clearly made evident by Cohen and Berstein's overview "Microparticulate Systems for the Delivery of Proteins and Vaccines". The Editors have attracted a reputable cadre of scientists in the microparticulate area, with definite emphasis on the design of novel particulate vaccines. This latter emphasis is well directed, as more progress in particulate vaccine systems has been made than in most other vaccine areas.

The Editors open the text with an overview of protein stability and delivery from microspheres, followed by nearly 500 pages covering novel polymers, new methods for encapsulation, and vaccine applications. This book has several strengths, and only a few weaknesses. Its coverage of microparticulates is exemplary, wherein the chapters flow more like a text drafted by a single author than a collection of individuals, and are directed towards readers interested in a broad overview of this area, rather than a hands-on manual, or a focused critical review of a single area (such as design of single shot vaccines, or toxicology issues with the use of novel polymers). Most chapters lack comprehensive tables showing related/prior technology in the immediate area, which would have greatly improved day-to-day utility of the book. This is compensated for by its extensive and timely chapter references, and its readability. This book is recommended to all researchers in the area of microparticulate protein drug delivery as one of the key reference books to rely upon, as well as for a general overview of hurdles and their solutions at this complex interface of engineering, chemistry, biology and immunology.

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Books Received

Biomaterials and Polymers

Biomaterials Science: An Introduction to Materials in Medicine. Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen, and Jack E. Lemons, Eds. Academic Press, Inc., 525 B Street, Suite 1900, San Diego, California 92101. 1996. xi, 484 pp., illustrations. $129.95.

Prediction of Polymer Properties, Second edition, revised and expanded. Jozef Bicerano, Author. Marcel Dekker, Inc., 270 Madison Avenue, New York, New York 10016. 1996. xvii, 528 pp., illustrations. $165.00.

Drug Development

Clinical Research in Pharmaceutical Development. Barry Bleidt and Michael Montagne, Eds. Marcel Dekker, Inc., 270 Madison Avenue, New York, New York 10016. 1996. xiv, 360 pp., illustrations. $135.00.

Models for Assessing Drug Absorption and Metabolism. Ronald T. Borchardt, Philip L. Smith, and Glynn Wilson, Eds. Plenum Press, 233 Spring St., New York, New York 10013. 1996. xxii, 444 pp., illustrations. $95.

Contents

1. General principles in the characterization and use of model systems for biopharmaceutical studies
2. Methods of evaluating intestinal permeability and metabolism in vitro
3. Cultured intestinal epithelial cell model
4. Intestinal rings and isolated intestinal mucosal cells
5. Models of drug absorption in situ and in conscious animals
6. Model systems for intestinal lymphatic transport studies
7. Buccal tissues and cell culture
8. Isolated hepatocytes
9. Cultured rat hepatocytes
10. Isolated perfused liver
11. Isolated renal brush border and basolateral membrane vesicles and cultured renal cells
12. Use of an isolated perfused kidney to assess renal clearance of drugs
13. Brain microvessel endothelial cell culture systems
14. Methods to study drug transport in isolated Choroid Plexus Tissue and cultured cells
15. Brain perfusion systems for studies of drug uptake and metabolism in the central nervous system
16. In vitro nasal models
17. Models for investigation of peptide and protein transport across cultured mammalian respiratory epithelial barriers
18. Drug transport across Xenopus alveolar epithelium in vitro
19. In situ and in vivo methods for pulmonary delivery
20. In vitro viable skin model
21. Isolated perfusion porcine skin flap systems
22. Vaginal epithelial models
23. Ocular epithelial models

Drug Information

British Pharmacopoeia 1993: Addendum 1995. UNIPUB, agent for HMSO publications, 4611-F Assembly Drive, Lanham, Maryland 20706. 1995. lxix, pp. 1493–1707, Appendices pp. A389–A483, illustrations. $135.00.

Strauss's Federal Drug Law and Examination Review. Steven Strauss. Technomic Publishing Company, Inc., 851 New Holland Ave., Box 3535, Lancaster, Pennsylvania 17604. 1996. vii, 434 pp., illustrations. Paper. $35.

Pharmacology

Immunopharmacology Reviews: Volume 2. John W. Hadden and Andor Szentivanyi, Eds. Plenum Press, 233 Spring St., New York, New York 10013. 1996. xiv, 443 pp., illustrations. $129.50.

Nonanticoagulant Actions of Glycosaminoglycans. Job Harenberg and Benito Casu, Eds. Plenum Press, 233 Spring St., New York, New York 10013. 1996., viii, 295 pp., illustrations. $89.50.

Pharmaceuticals

Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control. Sidney H. Willig and James R. Stoker, Eds. Marcel Dekker, Inc., 270 Madison Avenue, New York, New York 10016. 1997. x, 496 pp., illustrations. $99.75.

Protein Drugs

Protein Engineering: Principles and Practice. Jeffrey L. Cleland and Charles S. Craik, Eds. John Wiley & Sons, Inc., 605 Third Avenue, New York, New York 10158. 1996. x, 518 pp., illustrations. $69.95.

Contents

1. Introduction to protein engineering
2. Protein conformation
3. Predicting the conformation of proteins from sequence data
4. Expression of proteins in bacteria
5. Expression of heterologous gene products in yeast
6. Expression of engineered proteins in mammalian cell culture
7. Insect cell expression technology
8. Protein expression in Xenopus Oocytes
9. Mutational effects on protein folding: methodology, application, and interpretation
10. Successful protein folding on an industrial scale
11. Protein engineering for stability
12. Structure-function relationships for protein design
13. Bacteriophage display libraries
14. Design of metalloproteins
15. Engineering therapeutic antibodies
16. Site-directed mutagenesis of tissue-type plasminogen activator
17. Site-directed drug design

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