

Book Reviews

Inhalation Delivery of Therapeutic Peptides and Proteins. Akwete Lex Adjei and Pramod K. Gupta, Eds. Volume 107 of Lung Biology in Health and Disease, Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1997. xxxii, 913 pp., illustrations. \$225.00.

This is an extensive reference work integrating and broadly covering topics as diverse as lung physiology, protein chemistry, and aerosol aerodynamics. Progressively it covers methods of aerosol generation, delivery, and analysis of peptide-based drugs to both nasal and pulmonary regions of the respiratory tract. It presents four clinical examples of aerosolized peptide therapeutics: cyclosporin, interferon, α -1-antitrypsin (α -1-proteinase inhibitor), and deoxyribonuclease in five separate chapters.

The volume combines the expertise of 35 authorities in these disciplines into a well-organized volume focused on the problems and future promise of delivering peptide-based pharmaceuticals via the respiratory tract. Organized in 8 sections comprised of 27 chapters, it contains 86 tables and 176 figures of data, illustrations, and reference information. The authors organize and condense information from nearly 2,300 published articles into the book. The volume contains a bonus chapter covering the emerging field of gene delivery to the respiratory tract, and a chapter abstracting 136 world-wide patents in the field presented in tabular form.

The book's encyclopedic level of content, its extensive index of cited authors, and subject index make it an important reference. Its scholarship and readability makes it a necessary library addition for both basic and clinical scientists interested in peptide drugs, pharmaceutical delivery, and respiratory tract therapeutics.

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Development of Biopharmaceutical Parenteral Dosage Forms. John A. Bontempo, Ed. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1997. ix, 248 pp., illustrations. \$125.00.

This book is a broad survey of key aspects of developing protein pharmaceutical products, including both production of the bulk protein and the final dosage form. Eight chapters are included—an introduction, fermentation process events affecting biopharmaceutical product quality, development of recovery processes, preformulation development, formulation development, analytical techniques, membrane filtration technology, and elastomeric closure considerations. From the standpoint of the final dosage form, the book is limited in scope, covering only products marketed as aqueous solutions.

The book suffers from problems associated with most edited works, including gaps in coverage of the material as well as inconsistency in style. For example, the chapter on fermentation factors affecting product quality is a good subject,

but the author covers too much ground in not enough detail. The same is true for the chapter on downstream purification of proteins, which devotes only a paragraph or two to important separation operations such as size exclusion chromatography and ion exchange chromatography. Pyrogen removal is a critical step in downstream processing which can have profound effects on product quality, but the subject is not covered.

Regarding the preformulation chapter, the mechanisms of protein degradation, both chemical and physical, have been covered in great detail in the pharmaceutical biotechnology series edited by Ron Borchardt. A reader would be better off to consult one of the volumes in this series for preformulation-related background material. The idea of presenting stability case studies in the formulation chapter is a good one, but the text for this section consists of only a paragraph or two. It would have been helpful to the reader to have more detail presented.

The book does have some strong points. The chapter on filtration is good. It is well illustrated and goes into a reasonable amount of detail. Likewise, the chapter on elastomeric closures is a good overview of properties of elastomeric closures and ways in which the closure can affect product quality. While the book does have some value as an introduction to the subject, the content is too general to be used as a serious resource for the scientist or engineer involved in development of protein pharmaceuticals.

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Mechanisms of Transdermal Drug Delivery. Russell O. Potts and Richard H. Guy, Eds. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1997. ix, 357 pp., illustrations. \$150.00.

This book gives comprehensive information on the state of the art techniques used or potentially useful for assessing transdermal drug delivery. Much of the focus was on the techniques rather than on definitive discussions on mechanisms. Perhaps another title would be "Techniques to determine mechanism of transdermal delivery." However, most techniques are discussed in great detail, from the theory to the potential applications to the limitations. Furthermore, this is an extremely useful reference for investigators interested in finding tools available to help solve the question "What is the transdermal mechanism for a particular agent or enhancer." The discussions on the workings of specific enhancers are somewhat limited to the standards, e.g., oleic acid, ethanol and Azone. It is conceivable other enhancers were not discussed because of proprietary limitations.

Visualization techniques (direct and indirect) are very valuable adjuncts for deciphering transdermal mechanism (Chapter 1). Microscopic techniques provide an actual view of drug locale which is a very useful tool for making mechanistic deductions. The authors had an excellent overview table comparing the resolution and the advantages and disadvantages of available

visualization methods. Although many visual examples are provided, this chapter lacked the instrumental detail provided for in the other chapters. Chapter 2 on X-ray analysis is very detailed and would be applicable for the novice interested in understanding and using this technique for transdermal studies. Chapter 3 again provides a very detailed explanation on the theory and applications of infrared (IR) spectroscopy and differential scanning calorimetry. The authors provide useful insight on mechanism of some of the popular penetration enhancers (e.g., Azone and oleic acid) based on data generated by these techniques. The most useful section on the chapter on deuterium NMR (chapter 4) is the discussion of the comparison of NMR with other methods. The author goes over the differences relative to biases inherent in each method.

Fluorescence spectroscopy (FS) was used to study bilayer response to external stimuli (Chapter 5). It appears to be particularly useful for studying the presence of ions within stratum corneum bilayers during iontophoresis. The authors compare these findings to X-ray diffraction and IR spectroscopy results. They also note interpretation differences in FS methods to conclusions drawn from skin impedance measurements. Impedance spectroscopy is another method used to elucidate the pathways of ions through skin, discussed in great detail in chapter 6. Interestingly liposomes and monomolecular films are discussed in chapter 7 as a good medium for examination with neutron spectroscopic techniques. Based on the studies outlined, the techniques have potential for studying the mode of actions of skin penetration enhancers at the molecular level. Peck and Higuchi present a convincing overview, based on well thought out studies, on the existence of a "porous or polar pathway" in chapter 8. Finally, Chapter 9 gives a complete synopsis on data generated from iontophoretic studies. One can appreciate how versatile iontophoresis has become as a tool for enhancing transdermal delivery. Many tables are shown listing, complete with references, the agents tested to date, ranging from calcium to hyaluronidase, in transdermal clinical studies, *in vivo* animal studies and *in vitro* studies. There is also an insightful discussion detailing the iontophoretic pathway and that it may very well differ from a passive diffusion pathway.

Overall, this book describes in much detail, sophisticated methods to analyze the stratum corneum and in some detail the influence of enhancers and the transdermal absorption pathways.

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Enzymes—A Practical Introduction to Structure, Mechanism, and Data Analysis. Robert A. Copeland. VCH Publishers, Inc., 233 Spring St., New York, NY 10013-1578, 1996. xvi, 306 pp., illustrations. \$59.95.

Enzymes are important to an uncounted number of pharmaceutical scientists, be it as objects of study and/or experimental tools, or more marginally as parts of a scientific context. A good understanding of the structure, functions and experimental handling of enzymes is a necessity for many pharmaceutical scientists. I am grateful to the author for having written this truly exceptional book.

In just over 300 pages, the author has succeeded to offer an introductory textbook that gives guidance in laboratory protocols and data analysis, and at the same time provides the relevant scientific background. A rapid overview of the 11 chapters should be enough to convey the breadth and depth of the coverage, the logic of the argument, and the nice blend of theory and practice characteristic of this book. "A Brief History of Enzymology" is given in Chapter 1. This is followed by three basic chapters explaining "Chemical Bonds and Reactions in Biochemistry" (Chapter 2), "Structural Components of Enzymes" (Chapter 3), and "Chemical Mechanisms in Enzyme Catalysis" (Chapter 4). The next two chapters blend kinetics and experimental methods, namely "Steady State Kinetics of Single Substrate Enzyme Reactions" (Chapter 5) and "Experimental Measures of Enzyme Activity" (Chapter 6). Inhibitors are then examined in Chapter 7 ("Reversible Inhibitors"), Chapter 8 ("Tight Binding Inhibitors"), and Chapter 9 ("Time-Dependent Inhibition"). The last two chapters deal with more complex enzymatic cases, namely "Enzyme Reactions with Multiple Substrates" (Chapter 10) and "Cooperativity in Enzyme Catalysis" (Chapter 11). The book ends with three most useful addenda, namely an Appendix of American "Suppliers of Reagents and Equipment for Enzyme Studies", a short Appendix of "Useful Computer Software for Enzyme Studies", and a comprehensive subject index.

Because it is a single-author work rather than a disparate collection of reviews and compilations, this book is simultaneously coherent, homogeneous and perfectly well-balanced. And because its author is not only a broad practitioner but also an experienced and dedicated teacher, the book is both a pleasure to read and an inexhaustible source of information and knowledge. Its clear and didactic figures and its inviting style also contribute to motivating the reader. An invitation for further study is offered by the addition at the end of each chapter of a selected list of references and major monographs. In summary, "Enzymes" is a textbook that merits a visible place in the personal library of most pharmaceutical scientists. Some may use it to refresh and broaden their biological knowledge, whereas others, having studied it carefully, will find it a welcome companion in their daily work.

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Biosensors in the Body. Continuous *In Vivo* Monitoring. David M. Fraser, Ed. John Wiley & Sons, Ltd, Baffins Lane, Chichester, West Sussex PO19 1UD, England, 1997. viii, 258 pp., illustrations. \$45.00.

Biocompatibility Assessment of Medical Devices and Materials. Julian H. Braybrook, Ed. John Wiley & Sons, Ltd, Baffins Lane, Chichester, West Sussex PO19 1UD, England, 1997. xiv, 231 pp., illustrations. \$95.00.

These two books deal with seemingly different topics, but they in fact have many common grounds. The two books could have been combined into a bigger volume. The main focus of

the book "Biosensors" is in vivo glucose sensing. Since the in vivo glucose sensing inevitably requires implanting of glucose sensors and the resulting in vivo calibration, it is not surprising to see sections on biocompatibility in most of the chapters of the book. In addition, the book includes a chapter dedicated to biocompatibility of implantable devices. The chapter introduces the processes of biomaterial-host interactions and subsequent consequences for in vivo biosensors. The chapter on the exploitation of the foreign body capsule forming around the implanted sensors is not only informative but also intriguing. Other chapters on the use of electrochemical sensors and near-infrared spectroscopy all present objective views on the subjects.

The book "Biocompatibility" deals with, of course, the biocompatibility issue in more depth than the other book does. With a number of rather dramatic problems observed with implanted biomaterials and controlled drug delivery systems, the publication of the book "Biocompatibility" is very timely. This book includes information ranging from biocompatibility standards to sterilization processes to explant retrieval and analysis. Since many biosensors and controlled drug delivery systems need to be implanted in the future, the value of this book will increase in time. While each of the two books presents its intended information very well, the books collectively make a better reference source for biomaterials and biocompatibility. For those who would buy only one of the two books, I highly recommend to buy the other too.

Books Received

Analysis

Analytical Method Development and Validation. Michael E. Swartz and Ira S. Krull. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1997. 92 pp., illustrations. Paper. \$35.00.

The Handbook of Surface Imaging and Visualization. Arthur T. Hubbard, Ed. CRC Press LLC, 2000 Corporate Blvd. N. W., Boca Raton, FL 33431, 1995. xv, 909 pp., illustrations. \$179.00. (This book with 64 chapters describes all the experimental techniques currently available for imaging of solid surfaces (structure probing) and theoretical strategies for visualization of surfaces (conceptualization). This is an excellent reference book for biomaterials scientists).

HPLC Columns: Theory, Technology, and Practice. Uwe D. Neue. John Wiley & Sons, Inc., 605 3rd Ave., New York, NY 10157-0228, 1997. xiv, 393 pp., illustrations. \$89.95.

HPLC Methods for Pharmaceutical Analysis. George Lunn and Norman Schmuff. John Wiley & Sons, Inc., 605 3rd Ave., New York, NY 10157-0228, 1997. xxii, 1609 pp. \$150.00. (Detailed procedures for more than 160 drugs are described).

Pulsed Electrochemical Detection in High Performance Liquid Chromatography. William R. LaCourse. John Wiley & Sons, Inc., 605 3rd Ave., New York, NY 10157-0228, 1997. ix, 324 pp. illustrations. \$59.95.

Immunology and Pharmacology

From the Biological Clock to Chronopharmacology. Björn Lemmer, Ed. medpharm GmbH Scientific Publishers, Birk-

enwaldstraße 44, D-70191 Stuttgart, Germany, 1996. 206 pp., illustrations. DM/sFR 89.

New Horizons in Allergy Immunotherapy. Alec Sehon, Kent T. HayGlass, and D. Kraft, Eds. Plenum Publishing, 233 Spring St., New York, NY 10013, 1997. xiv, 480 pp., illustrations. \$129.50.

Medicinal Chemistry

Biotechnology of Antibiotics. Second Edition, Revised and Expanded. William R. Strohl, Ed. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1997. xi, 842 pp., illustrations. \$195.00.

European Drug Index. Fourth Edition. Niels F. Muller and Rudolf P. Dressing, Eds. Amsterdam Medical Press B.V., Houtil 3, NL-1811 JL Alkmaar, 1997. 1456 pp. DM/sFR 298.

Introduction to Medicinal Chemistry: How Drugs Act and Why. Alex Gringauz. John Wiley & Sons, Inc., 605 3rd Ave., New York, NY 10157-0228, 1997. xiii, 721 pp., illustrations. \$89.95.

Organic Reactions in Aqueous Media. Chao-Jun Li and Tak-Hang Chan. John Wiley & Sons, Inc., 605 3rd Ave., New York, NY 10157-0228, 1997. xi, 199 pp., illustrations. \$59.95.

Pharmaceutical Technology

Handbook of Pharmaceutical Granulation Technology. Dilip M. Parikh, Ed. Marcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602, 1997. x, 512 pp., illustrations. \$175.00.

Pharmaceutical Manufacturers: A Comprehensive International Directory. Swiss Pharmaceutical Society, Eds. Medpharm Scientific Publishers, P. O. Box 10 10 61, D-70009 Stuttgart, Germany, 1997. vii, 372 pp. DM/sFR 168.

Pharmaceutics

Therapeutic Protein and Peptide Formulation and Delivery. Zahra Shahrokh, Victoria Sluzky, Jeffrey L. Cleland, Steven J. Shire, and Theodore W. Randolph, Eds. American Chemical Society, 1155 Sixteenth St., N. W., Washington, DC 20036, 1997. ix, 228 pp., illustrations. \$89.95.

Scientific and Clinical Applications of Magnetic Carriers. Urs Häfeli, Wolfgang Schütt, Joachim Teller, and Maciej Zborowski, Eds. Plenum Publishing, 233 Spring St., New York, NY 10013, 1997. xiii, 628 pp., illustrations. \$149.50.

Selected Contents

1. Preparation and modification of biodegradable magnetic particles.
2. Characterization of magnetic particles.
3. Applications in cell separation and analysis, molecular biology, biomedicine, drug delivery, radionuclide therapy, MRI, and hyperthermia.

Polymers

Experimental Strategies for Polymer Scientists and Plastics Engineers. Richard C. Neuman. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. ix, 154 pp., illustrations. +diskette. Paper. \$62.50.

Polymeric Foams Science and Technology. Kishan C. Khemani, Ed. American Chemical Society, 1155 Sixteenth St., N. W.,

Washington, DC 20036, 1997. viii, 239 pp., illustrations. \$99.95.

Polymers and Copolymers of Higher α -Olefins. B.A. Krentsel, Y.V. Kissin, V.J. Kleiner, and L.L. Stotskaya. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. viii, 374 pp., illustrations. \$147.50.

Rheology of Polymeric Systems: Principles and Applications. Pierre J. Carreau, Daniel C.R. De Kee, and Raj P. Chhabra. Hanser Gardner Publications, 6915 Valley Ave., Cincinnati, OH 45244-3029, 1997. xiv, 520 pp., illustrations. \$197.50.

Others

The ACS Style Guide: A Manual for Authors and Editors. Janet S. Dodd, Ed. American Chemical Society, 1155 Sixteenth St.,

N. W., Washington, DC 20036, 1997. x, 460 pp., illustrations. Paper. \$26.95.

Creating Technology Strategies: How to Build Competitive Biomedical R&D. Alice M. Sapienza. John Wiley & Sons, Inc., 605 3rd Ave., New York, NY 10157-0228, 1997. xvi, 241 pp., illustrations. \$45.00.

Using Computers in Chemistry and Chemical Engineering. Theresa Julia Zielinski and Mary L. Swift, Eds. American Chemical Society, 1155 Sixteenth St., N. W., Washington, DC 20036, 1997. xiii, 385 pp., illustrations. \$39.95.

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