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Book reviews

Sarafaraz K. Niazi, in: James Swarbrick (Ed.), Handbook of Bioequivalence Testing, Drugs and the Pharmaceutical Sciences, vol. 171, ISBN-13: 978-0-8493-0395-1, £ 145

This book summarizes the field of bioequivalence testing in a comprehensive way starting from fundamentals to special topics. The chapters are consecutively arranged and well organized. Thus they are easy to read and to use.

The book consists of a total of 13 chapters and 3 appendices. The keywords provided within the index are appropriately selected and hence it is easy to find the right section. Starting with rationale and principles of bioequivalence testing the author presents a compact overview on basics concerning bioequivalence studies. Among others differences of various applications which have to be taken into account concerning bioequivalence studies are presented. Regulatory aspects and bioequivalence testing in the view of the FDA are represented in Chapter 2. In this context also surrogates of bioequivalence testing methods are reported which may be accepted by the authorities. Within the next chapter Pharmacokinetic and Pharmacodynamic modeling are briefly addressed. Chapter 4 deals with waiver of bioavailability/bioequivalence studies. Herein the biopharmaceutical classification system of the FDA is discussed and details on conducting alternative methods including data analysis, e.g. the Caco-2 permeation test, are given. 'Regulatory Review Process' informs by a point by point listing about what authorities demand to know during an audit process. Chapter 6 'Statistical Evaluation of Bioequivalence Data' introduces statistical models in theory and practice as well different available software programs. Moreover, concrete examples are provided. Physicochemical properties affecting bioequivalence are discussed in Chapter 7. Chemical aspects, e.g. influence of ionization, as well as physical properties, e.g. crystal properties, are addressed. Furthermore, information about dissolution testing is included. Within Chapter 8 'Drug Delivery Factors' the fundamentals of the previous chapter are related to various drug formulations and their application site covering a broad range from the more classical, e.g. tablets, suspension and emulsions, to therapeutic systems. In addition, the influence of physiological factors, like GI transit and transporter systems, is described. Chapter 9–12, 'Bioanalytical Method Validation', 'Good Clinical Practice', Good Laboratory Practices for Nonclinical Studies', and 'Computer and Software Validation', deal with requirements of the authorities. Due to the comprehensive, authentic examples included, these chapters are very valuable for practice. The Chapter 'Bioequivalence Reports' provides a practical guide to prepare reports for regulatory submission. Several well taken examples illustrate the way to report. The book closes with three appendices: 'Glossary of Terms', which is very helpful for the reader, 'Bioequivalence Testing Literature', and 'Dissolution Testing Methods of Approved Drugs', listing all drugs including the dissolution method reported to Food and Drug Administration until 2007. This list may be very helpful for practice. In contrast in the reviewer's opinion, although up to date, Appendix 2 is less informative, especially due to the possibility of data banc search nowadays.

Taking all together, the 'Handbook of Bioequivalence Testing' is an up to date summary of how to conduct bioequivalence studies and to avoid pitfalls with authorities. The inclusion of clear and practical examples makes the book particularly valuable to everybody, who is interested in bioequivalence studies. However, the reader has to keep in mind, that most of the detailed information which is provided is related to the American regulatory authority, the Food and Drug Administration.

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D.J.A. Crommelin, R.D. Sindelar, Bernd Meibohm (Eds.), Pharmaceutical Biotechnology: Fundamentals and Applications, third ed., Taylor & Francis, London, 2007, pp. 496, ISBN: 9781420067521, £ 125.

Pharmaceutical Biotechnology may be defined as the use of living organisms or their component parts in the processing of materials to provide pharmaceutical products, such as

therapeutics, diagnostics, supplies or additives. Traditionally these biological agents have been microorganisms, grown under controlled environment conditions on a suitable substrate. Typical pharmaceutical biotechnological products thus are antibiotics, steroids, vaccines, diagnostics and recombinant proteins. However, the term biotechnology has also been used if current scientific methods and techniques were applied to modify and improve a given biological system. The rapid development in molecular biology is an important driving force of modern drug discovery and clinical application. As a consequence, from time to time we need comprehensive updates reviewing the recent developments in the field. The editors of "Pharmaceutical Biotechnology" have accomplished this challenge to a high standard in the 3rd edition of their textbook which was revised and extended in many parts to reflect and emphasize trends and advances in pharmaceutical biotechnology. This undergraduate textbook is intended for pharmacists and pharmaceutical scientists in academia and industry and may also be informative for other readers interested in fundamentals and recent developments in the areas of pharmaceutical and medicinal biotechnology. The text explains both the basic science and the development and application of novel biotechnology-produced pharmaceuticals, with special emphasis on their clinical use as well. The book is divided into 24 chapters each authored by experts in the respective field covered. It includes the following chapters: 1. Molecular Biotechnology, 2. Biophysical and Biochemical Analysis of Recombinant Protein Structure and Analysis of Proteins, 3. Production and Downstream Processing of Biotech Products, 4. Formulation of Biotech Products, Including Biopharmaceutical Considerations, 5. Pharmacokinetics and Pharmacodynamics of Peptide and Protein Drugs, 6. Immunogenicity, 7. Genomics, Proteomics and Additional Biotechnology-related Techniques, 8. Gene Therapy, 9. Oligonucleotides and siRNA,10. Hematopoetic Growth Factors, 11. Interferons and Interleukins, 12. Insulins, 13. Growth Hormones, 14. Recombinant Thrombolytics and Coagulation Factors, 15–18. Monoclonal Antibodies, 19. Recombinant Human Deoxyribonuclease, 20. Follicle-stimulating Hormone, 21. Vaccines, 22. Dispensing Biotechnology Products, 23. Economic Considerations in Medical Biotechnology, and 24. Regulatory Issues and Drug Product Approval for Biopharmaceuticals. All chapters are well structured, easy to read and well illustrated. The potential purchaser and reader may be interested in what has changed since the 2nd Edition of 2002. The general chapters (1–5) remained nearly unchanged, including some errors (p. 51, the drawing of the airlift bioreactor is still incomplete). Chapter 6 is a new one, presenting and discussing the immunogenicity of therapeutic proteins. The chapters on monoclonal antibodies are completely reorganized and were divided into one general chapter and three chapters dealing with important applications (cancer, organ transplantation, inflammation). Finally, dispensing of biotechnological therapeutics, as well as regulatory and economic considerations now each has its own chapter. The literature survey is up-to-date. For example, the chapter on "Gene Therapy" (contributed by M.A. Croyle) cites 185 publications, 85 of which were published between 2005 and 2007, in the short chapter on "Oligonucleotides" (contributed by R.M. Schiffelers and E. Mastrobattista) 26 out of 43 references are newer than 2004. Self-assessment questions, which could be found at the end of most chapters of the 2nd Edition, were omitted in the 3rd Edition. In summary, this textbook comprehensively covers the basic science and clinical uses of novel biotechnology-derived pharmaceuticals and the paperback edition (£ 50) may even be affordable for students at Pharmacy and Medical Schools. Hence, this book may serve as an appropriate source for classroom use as well as for professional reference and further education.

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M.S. Roberts, K.A. Walters, (Ed.), Recension of the Book: Dermal Absorption and Toxicity Assessment, second ed. Informa Healthcare, 2007. ISBN-13: 9780849375910.

The second edition of this book provides again a decent overview on the current knowledge about dermal absorption and toxicity assessment. It contains a collection of articles dealing with all topics necessary to work with skin of different species and for various applications: from the morphology over *in vitro* test methods to *in vivo* test methodologies comprising formulation issues. This includes description of contact dermatitis and the corresponding impact of transdermal drug delivery systems and the toxic effects after absorption of substances. In addition the book provides detailed insight in approaches gaining more momentum right now and that will be of high impact in the near future. Methodologies to avoid animal testing as well as sophisticated *in silico* models to predict the penetration and toxicological effect of chemicals are also included. Several different approaches are sketched and weighted. This is also discussed with respect to regulatory affairs which are presented form different authorities. In this context, increasing relevance will be given to metabolic processes in skin in the near future what is reflected as well in two chapters of the book. The book is closed with some special examples regarding skin penetration and absorption for substances from different application fields.

What strengthens the book is the room it gives to contradicting arguments highlighting the actual discussions in the scientific community.