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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