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BOOK REVIEW

Pharmaceutical Bioequivalence
Edited by Peter G. Welling, Francis L.S. Tse, and Shrikant V. Dighe

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467 pages, hard cover, price $145 domestic, $166.75 foreign

Bioequivalence is a topic of great scientific and regulatory importance. Also, of course, it is a subject in which our knowledge is rapidly changing. This book is therefore most timely. It is edited by two industrial pharmaceutical scientists (one of whom is internationally renowned for his research in this field) and an official of FDA, who is widely regarded as one of the Agency's most knowledgeable scientists and an administrator who makes realistic judgments about bioequivalence whenever possible.

The sixteen chapters of which the book consists cover a quite wide range of subtopics. Part one (chapters one through eight) covers the general topic of bioavailability. Part two (chapters nine through eleven) is focused on species differences and pharmacodynamic models. Part three (chapters twelve through sixteen) is directed to regulatory aspects.

As with any multi-author book, there is variability in the style and depth of treatment

accorded to the various topics. Some readers may well find chapter eight "In Vitro Methods to Determine Bioavailability: In Vitro - In Vivo Correlation" somewhat superficial. Eight pages is hardly sufficient to deal in any useful way with a topic of such importance. Your reviewer could not find any substantial discussion of such important subjects as deconvolution by statistical moment techniques or the exciting potential (and limitations) of the flow thru dissolution cell for in vitro/in vivo correlation. This equipment has recently become official in USP. By contrast, chapter eleven (forty-two pages long) is a thoughtful and comprehensive review of the important area of Pharmacodynamic Models in Bioequivalence. It has eighty-seven references, some as late as 1990. (In general, references throughout the book are useful and up to date.)

In view of the present interest in international harmonization, section three may well be especially important to many readers.

In general, the balance of the book is satisfactory. However, your reviewer would like to have seen some topics covered in more detail (e.g., the role of in vivo chiral conversion on bioequivalence.)

This book will be a useful reference text for many pharmaceutical scientists. It is unfortunate that its price is probably going to prevent many individuals from purchasing this book.

STAFF REVIEW