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Journal of Pharmaceutical and Biomedical Analysis
20 (1999) 607

JOURNAL OF
PHARMACEUTICAL
AND BIOMEDICAL
ANALYSIS

Book review

***Impurities Evaluation of Pharmaceuticals*, Satinder Ahuja, Marcel Dekker, Inc., 1998. ISBN 0-8247-9884-8, 293 pages, US$135.00**

Questions revolving around the impurity content in bulk drug substances and their dosage forms are central to the successful (or unsuccessful) registration of a chemical entity. Even the presence of overwhelming favorable clinical trial results cannot overcome deficiencies in the Chemistry and Manufacturing Control section of a new drug application. Monographs which deal with this area are often heavily salted with regulatory citations and references to various ICH documents in their latest state of revision, but often the basic science is given all too short shrift. The present volume represents a most welcome presentation of a large body of fundamental information regarding impurities in pharmaceuticals.

The first chapter provides an overview, wherein the contents of the following eight chapters are defined in a clear and concise manner. Each section in the overview has the same name as a subsequent chapter, so prudent readers will consult the overview before proceeding on to the more detailed expositions which follow.

The other chapters in this volume are entitled, 'Regulations and Requirements for Controlling Impurities', 'Isolation and Characterization', 'Analytical Methodology', 'Synthesis-Related Impurities', 'Pharmaceutical Formulation-Related Impurities', 'Kinetic Studies', 'Stability Studies', and 'Applications'. Each chapter provides an adequate coverage of the described topic, although more extensive citation of leading literature references (especially general review articles) would have been desirable. Workers in any analytical area will happily find that the chapter dealing with applications is the most extensive.

The present volume provides a short and compact introduction to the topics that concern the qualification of impurity species in bulk drug substances and dosage forms. The old procedure of impurity generation, isolation, identification, and quantitation is certainly broadstroked in this book. Workers who have executed such studies in the past will find that this book summarizes what they should already know, but those coming into the field will benefit from its introductory stance. The greatest application of this new volume would be in courses covering pharmaceutical analysis, and I would urge its consideration as a text (or supplement) for such courses.

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0731-7085/99/$ - see front matter
PII: S0731-7085(99)00006-0