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Book review

Handbook of modern pharmaceutical analysis
Satinder Ahuja, Stephen Scypinski (Editors), Academic Press, San Diego, London. Series 'Separation Science and Technology', Series Editor Satinder Ahuja, 2001, Vol. III, pp. 566, ISBN 0-12045-555-2

This book is a third volume in the series Separation Science and Technology, edited by S. Ahuja. Analytical chemistry today plays a vital role in drug discovery, development, production and post-market support. The book 16 chapters bring the reader up to date on the current practices and requirements throughout the field of pharmaceutical analysis. The contributing authors, coming from both the industry and academia, seek to provide a review of pharmaceutical analysis as an integral and increasingly important part of an overall drug development process. The volume charts the long path from synthesis and identification of a new active compound to the stage of stability studies of the new drug.

The first chapter provides a concise and clear overview of modern pharmaceutical analysis, while emphasizing the importance of regulatory requirements. In the second chapter the reader is introduced to a significant role the combinatorial chemistry coupled to high-throughput screening plays in drug development today. Systematic and detailed physical characterization of pharmaceutical solids allows to reliably predict their performance. Chapter 3 describes various methods of solid-state analysis that are employed during development, formulation and production monitoring. Chapter 4 deals with degradation and impurity analysis for pharmaceutical drug candidates. Various methods for identification and isolation of both process-related and degradation impurities are briefly discussed. Guidance to residual solvent testing including water is presented. Useful flowcharts illustrate the logic behind degradation studies. Chapter 5 describes preformulation studies as an integrated effort 'among many research teams' with the goal of gaining information necessary for formulation development and drug product design. The reader is taken through various stages of preformulation studies. Analytical techniques used at every stage are described. Chapter 6 is concerned with solid dosage form analysis. The focus is on non-destructive and non-invasive techniques that do not alter the dosage unit. Spectroscopy (NMR, FTIR, NIR, Raman) and microscopy (light, polarized light, scanning electron and transmission) are demonstrated as powerful tools for determining the state of the API in the dosage form. Confirming a general trend for laboratory automation a convincing case is made for modernization of dissolution analysis by employing fiber optic probes. In Chapter 7 analytical support for development, production and release of parenteral dosage forms is discussed. A special emphasis is placed on the sterility testing, bacterial endotoxin testing and bioburden testing. Novel methods for drug delivery are the subject of Chapter 8. Various routes and delivery systems are discussed. Protein delivery is described utilizing insulin as an example. Oral, pulmonary, rectal, ocular and dermatological routes are included. Novel devices, such as needle-free injectors, implants and inhalers are described. An overview of compendial testing is presented in Chapter 9 while Chapter 10 outlines the considerations for method development with an emphasis on HPLC. Other separation methods, such as TLC, GC, supercritical-fluid chromatography and capillary electrophoresis are discussed. A view of setting up specifications as an evolving process from Research and Development stage to commercial manufacturing is offered in Chapter 11. At different stages of drug development specifications are the means for ensuring that quality and safety are 'built into' a drug product. The use of ICH guidelines for setting up the specifications is demonstrated. In Chapter 12 validation of pharmaceutical test methods is described in detail with the focus on HPLC. Included flowcharts make a useful tool in planning a validation and should be indispensable for training. Reference standards and analytical method transfer are discussed as a part of method development and validation process. Stability studies of a drug substance, excipients and of pharmaceutical product are the subject of Chapter 13. Analytical method transfer issues are detailed in Chapter 14. Chapter 15 describes the analytical documentation generated at various stages of drug development. The final chapter is an overview of electrophoretic microchip technology. Basic principles of this recent technique are discussed, as well as its operational characteristics.

On the whole this well-written and thoroughly edited volume brings the reader up to date on a wide range of subjects pertaining to analytics in pharmaceutical industry. The subject is presented in a clear and logical way, facilitated by numerous illustrations and practical examples.

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A large and current list of references providing for further reading is included at the end of every chapter. This volume will be a useful reference for anyone studying, teaching or practicing pharmaceutical analysis today.

Alexander Nezlin*
CTS Chemical Industries Ltd.,
Kiryat Malachi, Israel
E-mail address: sashan@cts.co.il

* CTS Chemical Industries Ltd., Hakidma St. 3, Industrial Zone, 83057 Kiryat Malachi, Israel. Tel.: +972-8-860-7607; fax: +972-8-858-7531.