

Book review

Drug Stability, Principles and Practices, third edition, revised and expanded, Edited by J.T. Carstensen and C.T. Rhodes, in Drugs and the Pharmaceutical Sciences, Vol. 107, Marcel Dekker, New York, 2000, ISBN 0-8247-0376-6

This book is for those committed to stability studies. It lives up to the description 'revised and expanded', with a rationalisation of content and additional new chapters mainly related to the conduct and regulatory requirements associated with stability studies. This reduces the heavy theoretical bias providing a mix of theoretical and practical information. The book is now jointly edited, rather than by J.T. Carstensen alone and in this edition external authors also contribute just under half of the chapters. However, this does not lead to duplication in content but the overall size has increased to almost 800 pages.

The theoretical chapters related to stability kinetics are for obvious reasons, stable! However, they do present an extensive overview of the subject and incorporate useful and updated literature and practical examples. One casualty in this area is the chapter on statistical analysis, which has been dropped. This seems strange since the potential outcome of any stability study is a regression plot with a confidence interval, a diagram that still features on the front cover.

Additional chapters cover assay development, clinical trial materials, stability testing in USA and Europe and the possible future trends. The assay development chapter is a useful expansion since in essence all stability testing originates from a validated analytical method. The clinical trials chapter provides practical information on the level of implementation of stability testing throughout product development. This leads neatly into the regulatory requirements for the stability testing of new chemical entities and products globally, in Europe and USA. Bizarrely intermingled with these topics are chapters on packaging and the stability of peptides and proteins. The former has metamorphosed into a practical industry based approach whilst the latter retains a theoretical and applied format.

This book is not suitable for under-graduates except, as a secondary information source when detailed information related to stability studies is required. However, if you are directly involved with stability studies this book provides a very useful reference source, which should be at least available in the library.

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