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Book Review

Pharmaceutical Stress Testing: Predicting Drug Degradation; S. W. Baertschi, ed. Taylor & Francis, Boca Raton, Fl, 2005, ISBN: 0824740211; Hardback. 482 pages

Stress testing of pharmaceuticals is undertaken to investigate degradation pathways of active ingredients and predict the shelf-life of drug products. Currently, there is no regulatory guidance available to facilitate scientists in these endeavors. The text, *Pharmaceutical Stress Testing: Predicting Drug Degradation*, offers practical approaches to investigate issues of stability. The book begins with an introduction that defines terms and provides historical and regulatory perspectives on stability and stress testing. The next chapter introduces the subject of stress testing as a predictive tool in drug product development. The authors focus on the most relevant degradation mechanisms, namely thermolytic, hydrolytic, oxidative, and photolytic pathways. Chapter 3 continues the discussion by providing an overview of the major mechanisms of chemical decomposition based on common functional groups. The following chapter presents a general guidance on the design, experimental set-up, and analytical aspects of chemical degradation. Oxidative susceptibility and photostability are highlighted in subsequent chapters. The use of microcalorimetry and computational chemistry as tools in stress testing is also presented. While the majority of the text is focused on stability of the active compound, two chapters are devoted to stability of drug products.

The text has a definite industrial perspective. For example, one chapter discusses the goals of stress testing at different stages in the development timeline. Comparative stress testing as a tool to evaluate changes in manufacturing processes, multiple sources of raw materials, and screen excipients is presented. An entire chapter on solid-state excipient compatibility is also included. The final chapter addresses frequently encountered problems and questions and is likely to be referred to quite often by scientists involved in stress testing. For example, advice is given as to "how much validation of analytical methods for stress testing is appropriate" and "how hard should a drug substance be stressed."

The text is written in a clear and concise manner. The goals of each chapter are clearly stated and the formatting makes it easy to quickly locate specific information of interest. The authors and editor have done a superb job of combining the theoretical, chemical, and practical aspects of stress testing. The majority of the chapters present case studies and serve as excellent examples of how the concepts discussed can be incorporated into a stress testing program. Obviously, the text is a "must have" for those involved in stability testing. The book is also an excellent reference for both industrial and academic scientists working in various areas of drug development.

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