Book Reviews

Stability Testing in the EC, Japan and the USA, Scientific and Regulatory Requirements. Edited by Wolfgang Grimm and Kurt Krummen. Wissenschaftliche Verlagagesellschaft mbH, Stuttgart, 1993, 272 pp., ISBN 3-8047-1215-0.

Stability studies provide evidence of how the quality of a drug substance or a drug product varies with time under the influence of temperature, humidity and light. These studies also enable recommendations for storage conditions, retest periods and shelf life. All countries have their own guidelines for stability studies. The aim of this book is to elaborate the basic principles of stability testing and to demonstrate the formal differences that exist among different countries. On the basis of this, a harmonized guideline may be established that will be accepted by many countries of the world. This book includes the lectures presented at the Second International Symposium on Stability Testing held on June 5–7, 1991 in Darmstadt. The revised draft for a harmonized guideline on stability testing of drug substances and drug products for the EC, Japan and the USA has also been included with these lectures. The contents of this book can be classified into four major sections: basic principles of stability testing; official requirements of stability testing in the EC, Japan and USA; harmonized guidelines for the stability testing; and, future prospectives of stability testing.

The first section consists of six chapters. Chapter 1 describes the basic principles of stability testing with all the necessary experimental requirements. The characterization and improvement of the stability behavior of drug substances are presented in the 2nd chapter. This is a well written chapter and includes various examples of physical and chemical instability. However, the references provided are not current or complete. A concise survey of excipient compatibility and its importance in the stability studies is presented by D. C. Monkhouse in the next chapter. This lecture has been restricted to solid dosage forms. K. D. Gneuβ has presented the prediction of drug stability by using new techniques and strategies. The evaluation of stress tests and long-term storage data, the differences between classical and new nonlinear regression analysis and the use of error propagation law have also been discussed in this chapter. This chapter has many typographical errors in the text. Errors also exist in equation 5 and 12. Steuer et al. have presented a critical review of HPLC, supercritical fluid chromatography and capillary zone electrophoresis methods and their use in the stability testing of pharmaceuticals. This chapter is too condensed and does not provide adequate examples. The last part of this section deals with the influence of packaging material on the stability of drug products. This is a very informative chapter, but the references provided are inadequate for a reader to follow some of the equations presented in the chapter.

The second section consists of five lectures. The first lecture describes the use of plastics for drug products. This is a very well-written chapter and includes various analytical methods used to determine the possible interactions in a formulation. The EC guideline for stability tests on active substances and the finished product is described by A. C. Cartwright, followed by the revised Japanese guidelines for stability studies by Y. Takeda. Both these chapters are well written, concise and easy to follow. The FDA Guideline for submitting documentation on the stability of drugs and biologics under revision is presented by C. Kumkumian, followed by a discussion of stability testing in relation to the guidelines in the EC, Japan and USA.

The third section of this book includes two lectures: the newest draft of the harmonized guideline on stability testing in EC, Japan and USA and the general concept of stability testing. Both these chapters are clearly written with appropriate examples. In the general concept chapter, the author has clearly presented twelve important principles to be followed in the stability testing of pharmaceuticals. The author has provided adequate examples and covered a wide variety of formulations.

The last section deals with the future prospectives in stability testing. The application of cyclodextrins and their influence on the stability of active substances, and their importance in the formulation of molecular encapsulation has been critically evaluated. Stability testing of biopharmaceuticals derived from recombinant DNA technology is clearly described in the last chapter. The authors have justified the use of multiple analytical methods for stability testing of these products with useful examples. The usefulness of real time stability data in the prediction of the shelf life of pharmaceuticals containing protein is also discussed in this chapter.

Overall, the editors have done a good job in presenting the need to reach a harmonized guideline on stability testing for the EC, Japan and the USA. The book is well edited, with minimal overlap between the chapters. However, many typographical errors exist in the text. Regulatory requirements in stability testing have been more emphasized in this book when compared to the scientific aspects. The inclusion of a subject index at the end of the book would have been beneficial. In conclusion, I will recommend this book to those readers involved in the development of stability testing of pharmaceuticals in academic and industrial environments.

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Heparin and Related Polysaccharides, Advances in Experimental Medicine and Biology, Volume 313. Edited by David A. Lane, Ingemar Björk and Ulf Lindahl. Plenum Press, New York, 1992, 384 pp., ISBN 0-306-44212-4.

This volume is a compilation of selected proceedings of the international symposium, Heparin and Related Polysac-

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