



Contents lists available at ScienceDirect

European Journal of Pharmaceutics and Biopharmaceutics

journal homepage: www.elsevier.com/locate/ejpb

Book Reviews

S.W. Baertschi (Ed.). *Pharmaceutical Stress Testing, Predicting Drug Degradation, Drugs and the Pharmaceutical Sciences*, vol. 153, Taylor & Francis, Boca Raton (2005).

The stability of drug substances and drug products has many challenging scientific and regulatory perspectives, and this volume is a concise state-of-the art review focused on the chemical stability of solid dosage forms.

In the thirteen chapters, fundamentals like reaction mechanisms and kinetics are covered and illustrated by examples from both the public domain and work contributed by the authors. The scientific perspective is complemented by discussions on industrial procedures, e.g. at what stage of product development to invest resources and time to elucidate stability issues, as well as preformulation and selection of excipients and problems of change management, such as supplementary studies required if the active ingredient is synthesized by another route or if excipients are obtained from a new source. The final chapter on “Frequently Asked Questions” gives practical advice concerning requirements of regulatory authorities and the interpretation of available guidance documents. Special attention is given to solid-state degradation, oxidation mechanisms and photolytic reactions.

The combination of general principles and examples in the central chapter “Stress testing – The Chemistry of Drug Degradation” is a gem and could be recommended reading for advanced undergraduate and graduate students in pharmaceutics as well as an introduction for newcomers to industrial laboratories. It is complemented by two chapters on “Analytical Considerations” and the “Role of Mass Balance”. A contribution on microcalorimetry explores the potential and limitations of this unspecific yet sensitive method.

Two contributions deviate from the main direction. In contrast to chapters, where chemistry is in the foreground, the one entitled “Physical and Chemical Development and Stress Testing of Freeze-Dried Pharmaceuticals” is focused largely on physico-chemical aspects of lyophilisation. In view of the complexity of the operation and the practical relevance, this is a welcome addition.

Computer-based methods, such as the Computer Assisted Mechanistic Evaluation of Organic Reactions (CAMEO) and the statistical design and analysis of stability studies are covered in the other chapters, but “The Power of Computational Chemistry to Leverage Stress Testing of Pharmaceuticals” gives an impression of future developments based on quantum theoretical and force field modelling and the tools which are becoming available for this purpose.

The editor, who is also a co-author of more than half of the contributions, is to be congratulated for this excellent compilation. It is highly recommended for both academic and industrial libraries, although a weak point should not go without notice: the index is subprime. Neither APIs nor excipients are referenced. In the course of reading, the reviewer has prepared a supplement, which is available by e-mail upon request.

Richard Süverkrüp
Pharmazeutisches Institut der Universität Bonn,
Lehrstuhl für Pharmazeutische Technologie,
Gerhard Domagk-Street 3,
53121 Bonn, Germany
Tel.: +49 228 7352 33; fax: +49 228 7352 68.
E-mail address: richard.sueverkruep@live.com

Available online 29 August 2008

doi:10.1016/j.ejpb.2008.08.018

Duncan Q.M. Craig, Mike Reading, *Thermal Analysis of Pharmaceuticals*, Marcel Dekker (2007). 416 pp., \$ 139.95. ISBN 978-0-8247-5814-1.

Latterly, thermal methods have attracted renewed interest within the pharmaceutical field. The book “Thermal Analysis of Pharmaceuticals” edited by Duncan Q.M. Craig and Mike Reading focuses on the theoretical background, measurement optimization and pharmaceutical applications of thermal methods. There was a long need for such a book since analytical development is receiving more and more attention in the pharmaceutical industry, even when the book in some parts appears not to be enough in depth for the advanced reader. The great attractiveness of thermal methods is also due to the fact that in preformulation the described analytical techniques are urgently needed, and thus they are receiving more and more attention. The book is clearly structured and presents a thorough exposition of thermal measurement techniques. Besides the documentation of the basic methods, there is given special emphasis on the techniques themselves in terms of their use and interpretation of data with respect to physical structure. In addition, the limitations of thermal methods are included. Furthermore, the book can be used handbook-like.

The first four chapters focus on Differential Scanning Calorimetry (DSC) including Modulated Temperature Differential Scanning Calorimetry (MTDSC). The basic knowledge on DSC including the newest developments is described with up-to-date references, followed by working instructions and pharmaceutical applications. Especially the chapter “Optimizing DSC experiments” is very helpful, since it presents method and details on practical working instructions. This chapter goes more in depth than other older textbooks and gives furthermore suggestions for reading. In addition, an overview on pharmaceutical applications is presented accompanied by recommendations for further reading. Polymorphism is of particular interest and described extensively, however, little is presented on excipients. It should be highlighted that the reader is warned to be cautious with glassy systems, which is indispensable if someone needs to work with these systems. The chapter on MDTSC gives basically an introduction to MDTSC combined with working instructions; however, much more examples can be found in the literature.