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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.

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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.

The following two chapters focus on Thermogravimetric Analysis. Besides a general overview, the instrument types are described in detail. In depth knowledge on working instructions for the practice with typical examples and kinetic equations is presented. Furthermore, it should be highlighted that the authors emphasize that Thermogravimetric Analysis cannot be used as a stand-alone method which should result in practical implications for new researchers in the field. Concluding the issue of Thermogravimetric Analysis, a literature overview on pharmaceutical applications is given.

The remaining chapters cover classical methods such as Thermal Microscopy, Isothermal Microcalorimetry and Thermorheology, as well as methods that are more recently developed such as High Sensitivity Differential Scanning Calorimetry (HDSC) and Thermally Stimulated Current Spectroscopy. The chapter Thermal Microscopy presents Thermal Microscopy as an additive method for corroboration of data; however, it does not cover the up-to-date knowledge in this area. The chapter on Isothermal Microcalorimetry describes in detail how to use this technique and refers for this purpose mostly to lactose as a basic example. Furthermore, suggestions to characterize polymorphs at the early stages of identification are given, which is extremely useful for preformulation scientists. The chapter on Thermorheology gives the background on both rheology and thermorheology, and is of special interest for the advanced reader due to its elaborateness regarding all aspects of thermorheology. The newer methods such as HDSC and thermally stimulated current spectroscopy which are presented at the end of the book bring to perfection the overview on thermal methods presented.

Summarizing, all of the most widely applicable methods are presented; however, the reader looking for a thorough description of coupled methods and practical data on coupled methods will be disappointed. He has to refer the frequent mentioning of the coupled methods in the different chapters and the frequently given warning to confirm the results obtained with one method by other methods or to interface one thermal method with a second measuring technique. As stated by the authors, it was not their aim to present the newest developments on coupled methods: such a characterization combined with practical suggestions would always be insufficient because of the highly diverse nature of these methods. As a result, it was much more relied on covering in detail the basic principles.

It might be disadvantageous that the book took longer time than intended. This can also be asserted after reviewing the actuality of the references of some chapters. However, it can be hoped that a second edition will be edited very soon since modern pharmaceutics are unthinkable without thermal methods.

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J. McGinity, L. Felton (Eds.), *Aqueous Polymeric Coatings for Pharmaceutical Dosage forms*, third ed., Taylor and Francis, London, 2008, 488 pp. 145 £. ISBN: 0-8493-8789-2

The book “Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms” in its Third edition edited by James W. McGinity and Linda A. Felton presents the state-of-the-art knowledge on Pharmaceutical coating. As in the previous editions, the various chapters cover the present knowledge on coating technology. Evi-

dently, it makes sense that the book deals predominantly with aqueous coating systems with special respect to dispersions, since these are the most recently launched innovations. A special emphasis was laid on plasticizers, additives and storage of coatings which are like recurrent themes over the whole book. All important coating materials are presented and most of the materials are described in depth with all details.

The book is clearly structured, consists of fifteen chapters and can be divided in four sections with respect to the themes covered. The first three chapters are dedicated to the basics of aqueous coating, followed by four chapters on analysis and characterization of the films, not neglecting problems associated with film formation.

The very first chapter gives a clear and distinct description of film formation with pseudolatex dispersions accompanied by many examples which are very useful for the practical scientists. The following chapter describes the working with core pellets which is important with regard to the more and more important pellet layering technique used for modified-release oral dosage forms. The methodology, conditions and considerations are described and this chapter is a natural follow-up to the first one. Finally, the third chapter describes advantages and disadvantages of processing equipment with practical examples, however, without covering much literature.

The second section covers mechanical properties of polymeric films and methods for film analysis, as well as defects in aqueous film coated tablets, their appearance, origin and theoretical background with suggestions how to avoid them. Both these issues were also discussed in the previous edition of the book. Two other chapters cover problems which are underrepresented in the literature as the adhesion of polymeric films and the influence of coloring agents. In both chapters the influencing factors and conditions are exhibited accompanied by various examples from the literature.

After these two more general sections, a thorough description of all most recently developed new materials as well as of those materials most frequently used is following. As natural for different authors, these four chapters are going more or less in depth. The formulation, process variables and problems associated with the development of ethylcellulose pseudolatex are presented. The description of polymethacrylate systems in chapter nine gives an extremely broad overview and covers everything one needs to know on polymethacrylates. The application of HPMC and HPM-CAS is covered in chapter ten dealing with modified as well as with pH-dependent release. Further materials of importance are presented in this section; however, for some previously launched materials the reader has to refer to the previous editions which might be of disadvantage for a new researcher in the field.

Finally, there follow four chapters on particle design, polymer interactions, coatings of biodegradable polymers and physical aging which cover further aspects to consider when working with aqueous coating systems or developing new materials.

Thus, the book gives an in-depth knowledge for everyone working with aqueous coatings. The high actuality of the book might also be attributed to the fact that some of the world's experts have contributed to this edition. Overall the book is extremely useful for new as well as for advanced researchers in industry as well as for academic scientists.

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