M. Adeyeye, H. Brittain (Eds.), Preformulation in Solid Dosage Form Development, Taylor and Francis, London, 2008, 596 pp., 130 £. ISBN: 978-0-8247-5809-7.

The book "Preformulation in Solid Dosage Form Development" edited by Moji Christianah Adeyeye and Harry G. Brittain is a practical handbook, a development course, and a systematical evaluation of all aspects of preformulation at the same time. Especially Brittain gives practical easy accessible examples which the reader can transfer to his own problems. Often questions which occur to the pharmaceutical scientist in preformulation are asked and thus urge the reader to transfer the presented data to his own problems.

The book is clearly structured and is basically organized due to the four stages of preformulation which follow up each other in a typical preformulation development. After the introduction the parts "Preliminary Preformulation", "Profiling the drug substance", "Development of the ideal formulation", and "Beyond preformulation" systematically approach the different stages of preformulation.

The introduction covers all topics to be considered before preformulation and emphasizes the need to think before experimenting in order to avoid errors and to save valuable time and money. This fact is also absolutely necessary in early preformulation and moreover it is advised to use available methods of prediction before performing unnecessary experiments.

The proposition of intelligent preformulation determines the second part "Preliminary Preformulation" covering molecular physical properties, analytical data analysis, crystallographic characteristics, and salt selection and terminates in the use of artificial neural networks (ANN) for intelligent preformulation design. Questions as 'Which crystal forms are possible?' or 'Which salt is the best?' are essential in early preformulation and thus determine the development course.

The third part deals with the topics related to the drug substance and highlights that a detailed knowledge of the drug substance is essential and determines further preformulation. Thus the API has to be known and particle morphology has not to be neglected and to be analyzed with appropriate methods. Especially the chapter "Preparation and identification of polymorphs and solvatomorphs" is extremely useful and presents a great many examples described in the literature. In the following chapter problems associated with X-ray diffraction, methods how to work with mixtures and practical suggestions are combined. It presents an overview on the use of X-ray diffraction methods for solid pharmaceutical materials. A description of spectroscopic, thermal, calorimetric and solubility methods completes the overview on essential techniques in preformulation. Besides the advantages and disadvantages of the presented methods advices are given which techniques are used and shall be applied in preformulation. Recent advances in the determination of glass transition temperature, the application of coupled methods, and the performance of stability measurements are presented accompanied by a great many of useful examples.

Finally the development of an ideal formulation is described. After a short introduction highlighting the essential facts what to consider before stating practical studies, drug-excipient interactions during solid dosage form development and the methodology or their evaluation are presented. Positive and negative interactions are covered accompanied by an up-to-date literature review of a great part of the current advances in preformulation. The basics of statistics useful for evaluation are given. This fourth part concludes with a comprehensive chapter on general factors to consider for dissolution testing, on the importance of batch to batch variation, on biovaiwers, on practical hints for dissolution testing, and on regulatory aspects.

The book concludes with the fifth very concentrated part on preformulation reports and essential regulatory aspects in preformulation. Practical advices how to report as desired by the FDA using Quality by Design (QbA) and applying Process Analytical Technology (PAT) are presented and the importance of the drugs physicochemical properties for regulatory issues is highlighted.

As stated in the introduction remarks, the book serves the industry scientists by having the regulatory authorities in mind, however it is also of interest for new and advanced researchers in the field. Overall this newly launched book on preformulation is as valuable handbook for industrial scientists as well as for all other researchers in the field. For advanced readers the broad coverage of literature examples is of special interest.

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Drug–Drug interactions, A. David Rodrigues, Second Edition, Informa Healthcare USA, Inc., (2008). 768 pp., € 178,–, ISBN: 978-0-8493-7593-4

Due to the increasing awareness on the importance of drug–drug interactions and the permanently growing market of approved drugs, this text book deals with one of the most important topics in drug development, drug research and drug therapy. This book covers the issue of drug–drug interactions with regard to pharmacokinetics, enzyme kinetics of cytochrome P450 enzymes, in vitro approaches of studying drug–drug interactions, and clinical and marketing perspectives. Even though many chapters of this text book are dealing with discussion and description of cytochrome P450 enzymes in terms of drug–drug interactions, detailed attention was paid to the increasing importance of drug transporters for drug–drug interactions.

Chapter 1 introduces pharmacokinetic and pharmacodynamic concepts. This is an advantage because this book mainly describes and discusses pharmacokinetic drug–drug interaction due to inhibition or induction of enzymes and/or transporters. Chapter 2 describes different in vitro enzymes kinetics of mainly cytochrome P450 enzymes with regard to drug–drug interactions. Chapters 3–5 provide detailed introduction of cytochrome P450 enzymes, UDP-glucuronosyltransferases and drug transporters, respectively. These chapters describe the main functions, pharmacological properties, as well as tissue distribution of the enzymes and transporters. The description of general methods characterising the function of drug uptake and efflux transporters in animals and humans in Chapter 5 provides the reader a clear overview about accomplishments and future challenges. I personally believe that this is of great interest because the research on drug transporters is a relatively new discipline. The next two chapters (6 and 7) describe in vitro models and approaches for studying induction and inhibition of drug metabolizing enzymes with the main focus on cytochrome P450 enzymes. Even if these two chapters are written mostly from an industrial perspective, academic researchers can also extract valuable information on the design of in vitro studies for basic research in pharmacology. The reader will be encountering difficulties and pitfalls of such in vitro studies. Chapter 8 covers the role of P-glycoprotein for drug disposition, highlighting the

ever-increasing awareness of the importance of drug transporters for drug–drug interactions in humans.

Chapter 9 deals with cytochrome P450 protein modelling and ligand docking. This chapter provides a clear overview about the possibilities and recent advances in cytochrome homology model-building methods and methods for modelling of cytochrome-ligand interactions.

The following chapter 10 discusses in great detail the role of the gut mucosa for drug–drug interactions. I believe that this chapter is very important because most of the drugs are orally administered. The relevance of the intestinal drug metabolism in comparison to the hepatic drug metabolism is demonstrated with several pharmacologically relevant examples. An advantage of this chapter is that it also covers intestinal sulfotransferases and UDP-glucuronosyltransferases, in addition to the mainly discussed cytochrome P450 enzymes. Because many clinically used drugs such as erythromycin are mechanism-based inhibitors, chapter 11 is dedicated to the in vitro kinetics and in vitro – in vivo correlation of mechanism-based inhibition of cytochrome P450 enzymes.

Chapter 12 completes the topic of drug transporter-mediated drug interactions. Here, the main focuses are the molecular mechanism and clinical implications. Furthermore, the following section provides a useful introduction into a metabolism and transport drug interaction database (DIDB) developed by researchers at the University of Washington, WA, USA.

Drug–drug interactions from a clinical perspective are discussed in the next chapter. However, a detailed discussion of reviews or original articles focusing on large patient numbers with regard to drug–drug interactions is missing.

I personally liked reading Chapter 14 in which in vivo probes for studying induction and inhibition of human cytochrome P450 enzymes are discussed. This chapter was written by the famous clinical pharmacologist Grant R. Wilkinson who sadly deceased. His chapter describes the rationale, development, validation and application of currently useful in vivo probes to assess the catalytic activity of specific cytochrome P450 isoforms in individual subjects.

Chapter 16 written by experts at the U.S. Food and Drug Administration provides a comprehensive overview regarding integrated approaches in assessing cytochrome P450 and P-glycoprotein mediated drug–drug interactions. The reader will learn what types of in vitro and in vivo studies are necessary in order to gain relevant information on possible drug–drug interactions.

The last two chapters cover drug–drug interactions with regard to a toxicology (17) and marketing perspective (18). In Chapter 17, toxicities of known drugs are discussed whereas in Chapter 18 the problems of marketing with inhibitor/inducers are described.

Taken together, this text book provides excellent and detailed information regarding drug–drug interactions. This book should be considered as a useful reference book for all industrial and academic researchers who are working in the field of drug–drug interactions.

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