

a few lines are devoted to mixing machines. The chapter is concluded by some statements on the mixing of liquids. As mixing devices paddle mixers, propeller mixers and turbines are described.

'Solid dosage forms' is the topic of Chapter 13. This is a bit strange as in the preceding chapters in agreement with the title of the book techniques and processes have been described. The author lists up a series of properties which are studied during the preformulation phase and continues with a very short overview (27 lines) on granulation. This is immediately followed by statements on the manufacture of hard gelatin capsules, (they 'are prepared by dipping manganese bronze pins into a bath of molten gelatin.') on the different capsule sizes and eventually on their filling. Another section deals with tablets. In a very condensed form compression of tablets is described. 'One method of evaluating tablet manufacture considers the effect of applied pressure on porosity of the compressed powder. Data may be plotted as the negative natural logarithm of porosity against applied pressure in the form of a Heckel plot. The slope is proportional to the yield value $1/3\Phi$.' The next statement is on the tooling of a tablet press. All issues are addressed in a very superficial way. No more than two statements on tooling, on coating or on chewable tablets are mentioned. Inhalation products as metered dose inhalers (MDI) and dry powder inhalers (DPI) are profoundly handled on 25 lines.

Chapter 14 (four pages) is devoted to 'Sterilization'. The section on thermal sterilization starts with 'The use of heat to sterilize depends on the magnitude (T), duration (t), and amount of moisture present: $t \propto 1/T$.' A few lines later the following general statement is made: 'Spores and vegetative forms of bacteria may be effectively destroyed in an autoclave employing steam under pressure, either 1.03×10^5 N/m² at 394 K for 20 min or 1.86×10^5 N/m² at 405 K for 3 min.' Obviously individual D numbers or the effectiveness F of a sterilization procedure are unknown to the author. Performing a sterilization process as described above without further precautions as sterile filtration would end in a disaster! It is surprising that at the end of the chapter the use of ethylene oxide as a sterilant is described. At least in the EU the use of ethylene oxide as a sterilant has already been forbidden for years.

The last chapter, Chapter 15, deals with 'Bioprocessing'. The first few sections describe 'Pharmaceutical water systems', this means pretreatment and sources of water, water for injection and methods to produce it, its storage and distribution as well as quality control and validation. After a short section on 'Cell Kinetics' some information is given on bioreactor design. Issues like rheology, mass and heat transfer, mixing, and shear are shortly addressed in the authors own way. The chapter is concluded with some profound remarks on 'Bioprocessing plant design' (14 lines) and on 'Protein purification' (less than one page).

In its preface the author makes the following statement: 'The efficiency, quality, and economy of manufacturing

depend on an understanding of the individual operations involved in processing.' This is absolutely correct. For a long time little attention has been paid to process engineering in pharmaceutical development and production. As process engineering has never been a part of pharmaceutical curricula most pharmacists are not familiar with its basic concepts. Insofar there is a need for textbooks on 'Pharmaceutical process engineering'. Unfortunately the book written by A.J. Hickey does not fill this gap. First of all the different topics are described in a too superficial way. Most physical problems are handled in a narrative way only. For a beginner it is too difficult to translate these statements in a formula which would allow him to work with it. On the other hand for most practitioners the statements are common place. The use of symbols is rather strange. This holds especially if for a given parameter different symbols are used. In the first part of the book flow rates, heat or mass transfer rates and other rates are abbreviated by upper case letters only. For an experienced reader this is certainly not a serious problem. However a reader not being familiar with process engineering may not recognize that 'rate' stands for a time derivative of a given parameter. In addition only few references are made. If citations are given often the corresponding articles have been published 20, 30 or more years ago. In summary it is difficult to identify a target group which might draw an advantage from reading this book.

Ingfried Zimmermann*

*Lehrstuhl für Pharmazeutische Technologie,
Universität Würzburg, Am Hubland,
Würzburg, Germany*

* Tel.: +49-931-888-5471; fax: +49-931-888-4608.

E-mail address: i.zimmermann@pharmazie.uni-wuerzburg.de
(I. Zimmermann)

PII: S0939-6411(01)00223-5

Drug Stability, Principles and Practices, 3rd Edition, revised and expanded

Edited by Jens T. Carstensen and C.T. Rhodes, Drugs and the Pharmaceutical Sciences, Vol. 107, Marcel Dekker Inc, New York, ISBN: 0-8247-0376-6, \$185

One might think that there would not be much new in the field of drug stability testing to warrant a 3rd edition of this book. As the editors mention in the preface, there have been no fundamental changes in the equations that govern chemical reaction. Nor has the underlying theory of processes such as oxidation or hydrolysis been revolutionised since the last edition of this work. There have, however, been substantial improvements in our knowledge of the stability and the stability testing of macromolecules. Just think about

all of those therapeutic peptides and proteins flooding onto the market. Additionally, the rather dry subject of regulatory affairs has been expanding enormously and having considerable influence on all of our work in the drug stability area. The FDA's Draft Guidelines for Industry is reproduced in an appendix to this book and encompasses 110 sides. Yes, it is clear that a new edition of this reliable, readable text is a valuable contribution and help to us all.

Many of the chapters are virtually unchanged over last edition, whilst other chapters are completely new. For this reason I will not review the contributions on solution kinetics, kinetic pH profiles, oxidation, catalysis, solid state stability, moisture, characterisation of solids, preformulation, HPLC, and packaging. We all know these chapters; they are good; they are useful reading for advanced undergraduates and also for graduate students and pharmacists working in industry. As it turns out, the 'dry' chapters

are in many ways the most interesting and informative. These include descriptions of industrial stability testing and computerisation of stability data, and regulatory aspects of stability testing in Europe. Turning to science, the chapter on stability of polypeptides and proteins is a little disappointing, and could have included much more relevant data on physical problems. Otherwise this is a highly recommendable new addition of a well-known, respected book.

Geoffrey Lee*

*Department of Pharmaceutics, University of Erlangen,
Erlangen, Germany*

* Tel.: +49-9131-8529552; fax: +49-9131/8529545.