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Book review

'Arzneiformen-Entwicklung' ('Drug Dosage Forms Development'). Feste Zubereitungen (Solid Forms). H. Stricker, Springer Verlag, Berlin Heidelberg New York, 1. ed., 2003, 500 pages (in German), Price: 44.95 euro; ISBN 3-540-00068-2

The declared intention of the author is 'to select and to classify for a science driven development the expert knowledge of pharmaceutics, which was accumulated during the last decades. It should be possible with the help of arithmetic calculations done by available expert systems, to obtain quantitative prognoses about optimal amounts of auxiliaries, process conditions and product specifications' (translation from the reviewer).

The book is based on five PhD theses, written in the author's laboratory during 1995–2001 and not yet published elsewhere. Described are the process development of powders (for hard gelatin capsules), granulates (wet granulation), extrusion-pellets, tablets (dry compressed and from wet granulation), coated tablets as well as gastric juice resistant and slow release coated pellets.

All material specifications and equations get so-called security factors, e.g. SF = 1 high, SF = 0.2 questionable and SF = 0 no reliability. The results of the different phases—1st phase: development problems; 2nd: development steps; and 3rd: activities at the distinct steps—have a prognostic value for different product specifications. An example is the strength B of tablets compressed from granulates:

$$B = \left(k_{GB} + 1.5 \times d_w \times k_B \times X_B\right) \times B_A \exp \Phi_{SA} \times B_F \exp \Phi_{SF} \times B_{Fä} \exp \Phi_{SFä} \text{ (MPa)}, \quad (SF = 0.5).$$

where k_{GB} = fragility-effect; d_w = binding-force constant; k_B = binder-constant; X_B = mass fraction of binder, B_{index} = norm-value of A (active drug), F = filler, Fä = external filler, and Φ_{index} = volume fraction of A.

Of course, much more quantitative analytical methods as usual are necessary. These are elaborated in the mentioned theses and are listed in an abridged version in the annex.

Whom for? There are three possibilities: (a) the descript methods, procedures and arithmetic calculations are trustworthy in the daily practice of industrial development work; then the book will be a sensation and the most important one in its class nowadays. (b) The amount of data accumulated in only five PhD theses is still too small, but the principles are correct; this would also be a milestone in pharmaceutical technology. (c) The abundance of still missing parameters of material specifications, process conditions and product specifications, as well as interactions may be too large and complex so that traditional development approaches—scientific and empirical know how and the use of optimisation strategies—are more effective and less costly.

It would be a big advantage if the book could be translated into English as the Anglo-Saxonian colleagues are traditionally more interested in theoretical approaches. Maybe Springer New York is interested in this.

Heinz Sucker
CH-Basel,
Basel, Switzerland

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