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ScienceDirect
International Journal of Pharmaceutics 336 (2007) 396
INTERNATIONAL JOURNAL OF PHARMACEUTICS
www.elsevier.com/locate/ijpharm

Book review

Handbook of Preformulation. Chemical, Biological and Botanical Drugs, S.K. Niazi. Informa Healthcare, New York (2007). $ 115.00, ISBN: 0-8493-7193-7

Preformulation studies exhaustively and intelligently carried out can facilitate medicines development. Sometimes one wonders whether it is always on the critical development path as it should be, for formulators are sometimes left with difficult drugs which are to be formulated in a limited period. This prevents the application of the best pharmaceutical science which might dictate the choice not only of salt or crystal form but even of a drug analogue. The science of formulation still needs greater predictive powers and good textbooks. Here is one such book, which moves us closer to quantitation and prediction.

This is one of the most comprehensive texts on the topic of preformulation that I have come across. It is a veritable *tour de force*, especially given that it is written by a single author. Its 446 pages contain a wealth of information for the experienced and the apprentice formulator, as well as undergraduate students in pharmacy and postgraduate researchers. The book begins with a short chapter on drug discovery trends and another on intellectual property issues before describing the scope of preformulation studies. The book then treats a variety of key topics in depth, starting with dissolution, partitioning and solubility, then release, dissolution and permeability. Solid state properties and dosage form considerations are given chapters each and there is a discussion on the characterisation of synthetic drug substances. The subtitle of the book – chemical, biological and botanical drugs – is justified by separate chapters on the characterisation of biopharmaceutical drugs and phytomedicines, the latter often neglected in such accounts. There is a useful glossary of terms, a comprehensive index and voluminous bibliography.

The above outlines the structure of the volume. Closer inspection shows the detailed discussion of topics which are still the subject of research and concern. Many pages are devoted to discussion of recent studies reported in the literature. One such section addresses topics such as the biopharmaceutics classification system (BCS) and quantitative permeability studies, biomimetic artificial membranes, the blood brain barrier (BBB) and microdialysis, novel models of the BBB, through to snake skin models of percutaneous absorption. With each topic there is a critique of the original cited studies. A table of common crystal habits cites 36 habits, their descriptors and examples, the most comprehensive this reviewer has encountered. Many examples of decision trees are provided for dosage form selection, salt selection, and acceptance criteria for dissolution amongst other topics.

It is difficult to criticise such a comprehensive book, except perhaps that the treatment of excipients is relatively meagre. To what extent does variability in excipients and excipient engineering affect preformulation studies, for example. This is partially offset by some useful tabulation of the ingredients of approved biological products, information which is difficult to find elsewhere. All in all this is an excellent book which underscores the difficult science of preformulation and formulation. It certainly deserves a wide readership.

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24 January 2007

Available online 12 February 2007

0378-5173/$ – see front matter
doi:10.1016/j.ijpharm.2007.02.007