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Book review

Leon Shargel, Isadore Kanfer (Eds.), Generic Drug Product Development: Solid Oral Dosage Forms Drugs and the Pharmaceutical Sciences, vol. 143, Marcel Dekker, New York, 2005, pp. 1–381 (420 pp.), £100.00, ISBN 0-8247-540.

Worldwide, there is growth in the demand for low cost generic pharmaceutical products, as individuals, governments, hospitals, health maintenance organisations and other institutions seek to control their drugs' budgets. The development process for generic pharmaceutical products differs from that of innovator branded products. Manufactures of generic pharmaceuticals must formulate and manufacture a product having an equivalent in vitro performance, safety and therapeutic efficacy to the branded innovator reference product, i.e. it must be therapeutically equivalent and bioequivalent.

This book provides a comprehensive overview of the process of bringing a generic pharmaceutical product to market, from selecting which product to market, to product development and testing, scale-up and the legislative and regulatory hurdles to be overcome prior to licensing. To this end, the book comprises 14 chapters which describe the various steps in this process. This makes for interesting and varied reading. For instance, there are detailed chapters on Analytical Method Development and Experimental Formulation Development, which describe in general terms analytical method development and validation and optimising formulation performance whilst providing experimental data with explanations to illustrate key points made. The chapter on Bioequivalence and Drug Product Assessment, In Vivo is a good introduction to bioequivalence, which is key to success in the development of a generic product, and is a subject prone to neglect in undergraduate pharmacy courses. Another chapter, "ANDA Regulatory Approval Process", is enlightening in its description of the process for filing applications for generic products with the US Food and Drug Administration. A substantial checklist for assessing the completeness and acceptability of an application is included.

Overall, the book is well written and edited. There is a good blend of authors from academia, the pharmaceutical industry and the FDA. However, only 3 of the 35 authors are from outside the USA, with none from Europe or Japan. This is reflected in the book's content, which is highly focussed on developing and testing products to meet the requirements of FDA's regulatory approval processes.

I have only one criticism: the index is inadequate for a book containing so much detailed information. For instance, key terms such as dissolution testing, excipient, particle size, polymorphism and solubility are absent from the index even though the subjects are covered in the text.

In summary, this is a well written book which will be useful for those working, or having an interest in generic pharmaceutical manufacture and regulation. Despite the book's focus on the development of oral solid dosage forms, it contains much which is equally applicable to other generic pharmaceutical products.

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