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Book reviews

Containment in the Pharmaceutical Industry
J.P. Wood, editor, Marcel Dekker, New York. Series 'Drugs and the Pharmaceutical Sciences', 2001, Vol. 108, ISBN: 0-8247-0397-9

The book informs about the evolution of containment approaches for pharmaceutical compounds and processes, a relatively recent topic in pharmaceutical manufacturing operations. Instead of focussing on specific containment-related topics, such as barrier technology, isolator applications, and aseptic isolator designs, the book finds a niche in taking a more holistic view of containment overall, as applied and achieved in the industry. Because there is no universal industry agreement on methods to contain, the objective of the book is seen in the exploration of the main elements of containment as it is currently practised by various members of the industry. Therefore the contributing authors' experience is covering the topics from several perspectives, i.e. that of the large pharmaceutical industry, engineering firm's perspective along with consultants' and academic institutional views.

Specifically the book first presents a brief historical perspective of containment in the industry, a workable definition of the term, and containments' relationship to other industries. Along with initial definitions, a chapter focussing on some recent research of what makes powders 'dusty' and how that is being defined, quantified, and used in the containment design is included. The book discusses approaches for both new and retrofitted installations, and there is discussion of 'people protection' versus 'product protection' and source containment's potential role in each.

Several examples illustrate that a project's planning, design, construction, and start-up commissioning phases must all reflect the various containment provisions and philosophies with which the project began. Consequently the book is of interest to those who are responsible for the planning, design, building, and start-up activities of projects that have containment elements. Also those individuals that are responsible for meeting the containment criteria for ongoing operation and maintenance of contained processes have an interest in the topic as well. Thus the book can be regarded as a tool among several others, which can be useful in the quest to better contain pharmaceutical operations. In particular, and since there is often more than one possible solution to a containment problem, the better the decision-maker understands the operation in question, the more an informed selection can be made of which approach to pursue.

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Oral Drug Absorption: Prediction and Assessment
Jennifer Dressman, Hans Lennernäs (editors), Marcel Dekker Inc., New York, Basel, pp. 330, ISBN 0-8247-0272-7

Volume 106, entitled 'Oral Drug Absorption' has appeared in the distinguished series of textbooks and monographs on 'Drugs and the Pharmaceutical Sciences' by Marcel Dekker. Two well-known experts in the field; J. Dressman and H. Lennernäs, assisted by 20 co-authors undertook the task of giving a comprehensive overview about one of the key questions of drug development: the bioavailability of drug candidates after oral administration and the factors contributing to it.

The book is divided into four sections each containing three to five chapters. The first section is dedicated to physiological aspects such as transit time in different segments of the GI-tract or disease states affecting drug permeability across the gut wall. The pathophysiology, mechanisms and symptoms of maldigestion and malabsorption are explained by means of clinically relevant examples. The second section outlines the assessment of intestinal permeability, ranging from theoretical calculations to in vivo perfusion studies in animal and man. It starts with a chapter on physicochemical parameters, which may be used to predict the absorption of a given drug in vivo and is followed by a chapter giving an overview about the in vitro models currently being used to determine drug permeability. The next two chapters discuss in detail the methodologies of animal GI perfusion and applicability of an intestinal perfusion technique in men. The final chapter of this section discusses the role of permeability studies from the viewpoint of the pharmaceutical industry. It emphasizes

the increasing need for preclinical studies in drug development and describes several exemplary case histories of permeability studies in the preclinical evaluation of novel drug candidates. Section 3 emphasizes the importance of drug solubility and dissolution for the overall bioavailability. After a chapter about the prediction of fraction dose absorbed dependent on solubility of passively absorbed drugs, two chapters describe dissolution testing of immediate and extended release products. Again, a chapter is devoted to the industrial perspective. It demonstrates in a series of case examples the complexity of a rational employment of various dissolution rate measurements in drug development. The next chapter gives a deeper insight into the analysis of drug dissolution data thereby discussing aspects like multipoint assessment of dissolution characteristics, analysis of cumulative dissolution profiles, comparison of dissolution profiles or handling of in vitro dissolution for predicting in vivo performance of oral dosage forms. The last section of the book is devoted to in vitro in vivo correlations. Different types of correlations are discussed and mathematical procedures of convolution and deconvolution are explicitly explained.

This new volume of 'Drugs and the Pharmaceutical Sciences' is a well written black and white illustrated book, which provides comprehensive information in a clear and user-friendly manner. It accomplishes its intention to discuss the key factors involved in drug release and passage along and across the GI-tract. All chapters are presented to a high standard. However, considering the very broad scope of intestinal drug absorption, it becomes clear, that not all aspects can be treated adequately. Drug metabolism is mentioned only on the verge. However, in their preface the editors refer the readers to more specialized books covering that special topic of drug absorption. In summary, the book is a useful guide to many people working in the field of oral drug absorption.

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