

Book Review

Pharmaceutical Dosage Forms: Parenteral Medications Volume 1, 2nd Edition

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This book forms part of a 3-volume set which is a standard reference work for the formulation and manufacture of parenteral dosage forms. It is an extension of the earlier 2-volume set which formed the first edition of the same name; the authors also list the contents of the remaining two volumes, as well as the updated contents of the parallel series on tablets (3 volumes) and disperse systems (2 volumes). This is useful since the potential user of these books is likely to need to refer to all 3 volumes in the course of his work, and will probably find much of interest in the rest of the set. For example, the parenteral formulation series overlaps to some extent with the disperse systems series, and anyone interested in, for example, intravenous colloidal systems, will need to refer to both series (possibly an expensive business!). This volume covers formulation and product development aspects of parenterals; volume 2 is more concerned with manufacturing, while volume 3 discusses the various aspects of quality assurance, recording, GMP and regulatory aspects.

This book, like all in the series, is an edited multi-author volume. The main problem with works of this type is that the standard of the separate contributions can vary, and material can be omitted or duplicated. This has largely been avoided in the present volume by careful choice of authors and (presumably) by editorial control, based on the first edition, so that the coverage of the area is very comprehensive. The authors are drawn from American pharmaceutical industries and universities, and so the bias is towards current American practice and FDA standards. This does not, however, lessen its value to the European user.

Chapter 1 is a broad overview of parenteral medication, including a historical perspective. It contains a useful glossary of terms. Chapter 2 is a discussion of the clinical aspects of parenteral systems, covering administration, distribution, hazards, precautions, and side-effects. Administration equipment (cannulae, filters, implantable pumps) is also covered briefly. This chapter is a summary of the area rather than a detailed review, essentially to provide background for the pharmacist. Chapter 3 covers biopharmaceutics of injected formulations, and discusses the importance of physicochemical factors such as drug pK and partition, followed by distribution in body compartments and pharmacokinetics, and bioequivalence, together with real examples (insulin, GRH, etc.). The new

student would find an introductory pharmacokinetics text helpful at this point. Chapter 4 moves on to preformulation factors of importance in the development of parenterals. All the important factors are discussed, including physicochemical properties, solubility, stability, crystal properties, spectroscopy, DSC, and compatibility, including packaging (there is some overlap with later chapters here).

The next two chapters move on to the formulation of small and large-volume parenterals, respectively. Formulation principles and testing are covered, with a little overlap with earlier chapters. This is followed by two more specialized chapters discussing the formulation of biotechnology products such as peptides, which mainly concerns itself with the important problem of degradation and additives to prevent it, and sterile diagnostics, which has a particularly good discussion of microbiological control. The next chapter on glass containers discusses types of glass, manufacture, testing, and stability, and is followed by a chapter on plastics and their applications, including properties, additives, fabrication, compatibility and testing. An extensive chapter on elastomeric seals covers materials, manufacture, performance and testing. The final chapter, parenteral products in hospital and home care pharmacy practice, discusses the use of parenterals in the pharmacy, including topics such as storage, handling, sterile compounding, and end-user quality assurance.

The book provides a good coverage of its subject areas but the reviewer found many places at which it would have been useful to refer to other volumes in the series. In particular there is very little material concerning colloidal parenterals (fat emulsions, TPN, fluorocarbon emulsions), and most of this material is in the companion volumes on disperse systems. The emphasis of the present volume is on general aspects of formulation and product development, and it is particularly strong on packaging (about a quarter of the book is devoted to this subject).

Two groups of people in particular will find this book useful; newcomers to the field of parenteral development and formulation, who need to absorb a large amount of interdisciplinary work in a short time, and experienced workers who want to expand their knowledge sideways to related areas. It is a useful reference for the fundamental aspects of parenteral pharmacy, but it is unlikely that experts at the forefront of their field could use it to review very recent developments; it is much better suited to the advanced graduate course, and to training of industrial technical staff, who will find it invaluable. The entire series is probably the best source for information of the disparate multidisciplinary area we call pharmaceuticals, and is essential reading for all in this area.

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