

Although emulsions have been used in pharmaceutical formulation for many years, it is probably fair to say that they have not achieved their full potential, particularly for parenteral drug delivery. This probably stems from their being perceived as 'difficult' systems, expensive to research and troublesome to develop. It is certainly true that they require a substantial investment in knowledge if they are to be developed into successful products, but given suitable information there is no reason why they cannot successfully be used to solve complex formulation problems, avoiding yet another hydrophobic drug from being thrown on the scrapheap of wasted investment.

Thus the potential reader will approach this book asking how much of this required knowledge could be gleaned from it. The answer is, quite a substantial amount, although some areas are better represented than others. The book is organized on a contributed chapter basis, and thus the contents reflect to some extent the activity in the field and the specific interests of the authors. Thus, for example, there are several chapters on solid lipid nanoparticles, and an extensive review on perfluorocarbon oxygen transport emulsions.

The first section of the book (three chapters) discusses intravenous fat emulsions, including chapters on structured triglycerides, particle sizing methods, and biofate and biodistribution. The second section opens with a very general review by Benita and Klang which gives an overview to the field and would have perhaps been better as the introductory chapter. This is followed by a chapter on topical emulsions, and three chapters on solid and supercooled lipid dispersions, covering this area in some detail. The book closes with a review of fluorocarbon emulsions, a field which has already been fairly heavily reviewed in the literature, although this probably is the most complete and up to date summary which this reviewer has seen.

All the chapters are presented to a consistently high standard although they vary in specialization. The book certainly covers a substantial portion of the area and would be a useful introduction to anyone contemplating the use of emulsions, particularly for parenteral use.

C. Washington

Department of Pharmaceutics
School of Pharmaceutical Sciences
University of Nottingham
Nottingham
UK

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Filtration in the Biopharmaceutical Industry

Theodore Meltzer, Mike Jornitz (editors), Marcel Dekker, New York, 1998, p. 933, \$225.00, ISBN 0-8247-9896-1

One of the co-authors, Theodore Meltzer, published his classic reference 'Filtration in the Pharmaceutical Industry'

more than 10 years ago. Although 12 years have past, much of the content of this book is still pertinent today. David Pall notes, however, in the foreword to the present volume, that much has changed or involved in the pharmaceutical industry, particularly in its biopharmaceutical areas, and also in the filter industry. This warrants an update to Meltzer's first work. Pall lists the need for smaller micron removal ratings than 0.2 μm , integrity testing (validation), protein and preservative binding, documentation and filter extractables. These points, and others, are covered in admirable detail and clarity in this multi-authored work. Indeed, this book assumes a certain biblical significance. I quote from the editors preface: 'There is a tradition of some 2000 years or more that holds that the good Lord undertook creation for the benefit of all humanity, but that each of us is so individual that in effect all of creation was manifest as if intended totally for each. From this it is concluded that one who preserves even a single life saves creation entire. The pharmaceutical and biotechnical industries being dedicated to mankind's well-being and longevity, the contributors to this book may have striven to attain this goal'. I found this opinion very congenial, and expected great things from the book: I was not disappointed.

The book is divided into five parts. Part 1 discusses the various types of filter used in the biopharmaceutical industry. There are chapters on filter aid filtration, expanded PTFE-membranes, charge-modified filters, pre-filters, and cartridge filters. These chapters present more a comprehensive overview of currently available filters, rather than just the developments of the last 10 years. At very best one of the chapters contains 50% of references from the 1990s: the other chapters have much less. Part 2 discusses filter characterization, with chapters on quality assurance, pore size and extractables. The final chapter is particularly readable and contains numerous practical examples of extractables and particle shedding from filters, a lot of which surprised me. Surely, this information is vital knowledge for the pharmacist in charge of parenteral production.

The section entitled 'Utilitarian Considerations' describes partly filter hardware and partly filter working and testing. Thus there are chapters on bacterial biofilms, filtrative particle removal from liquids, filter integrity testing, sizing membrane filters, filter housing materials and filter housings. This is all solid, basic stuff, but again only a small proportion originates from 1990s literature. However, the chapter on filter integrity testing will be particularly valuable for the practical industrial pharmacist. Similarly, I like the very practically oriented chapters on filter housing materials and filter housings. If you are involved with the manufacture of large or small volume parenterals, then there is much of direct practical relevance for you in these chapters. Part 4 entitled 'Applications' describes a host of practical situations concerning filtration. We find, for example, chapters on protein adsorption, filtration of viruses, air filtration, and sterility testing. The chapter entitled 'New Membrane Based Technologies for the

Pharmaceutical Industry' makes very interesting reading, and contains indeed 80% references from the 1990s. Finally part 5 considers regulatory aspects. Chapters with this title are usually tucked away at the back of books, but frequently make interesting, relevant reading. Consider, for example, the title of Chapter 27, 'The Operation of the FDA' which sounds like something from a book about espionage! Also, the chapter on validation of filtrative sterilisation, written by the two editors gives a clear description of the practice of validation ending with a brief outline of responsibility for validation. As the authors so correctly state, the responsibility for validation remains exclusively that of the drug

manufacturer. To understand the claims of the filter companies, however, the drug manufacturer (i.e. the production pharmacist) needs the knowledge contained in this relevant, comprehensive book.

Geoffrey Lee

Department of Pharmaceutical Technology
Friedrich-Alexander-University
Erlangen
Germany

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