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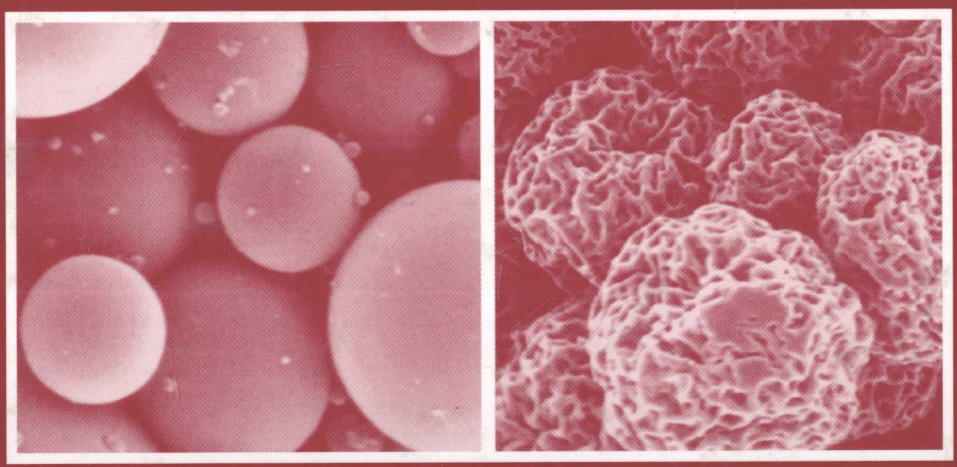
Injectable Dispersed Systems

Formulation, Processing, and Performance



edited by
Diane J. Burgess

Injectable Dispersed Systems

Formulation, Processing, and Performance

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This book is dedicated to my parents
Violet Isabel Burgess and George Gartly Burgess.

Preface

With the increasing number of biopharmaceutical products, the emerging market for gene therapeutics, and the high proportion of small molecule new drug candidates that have very poor solubility, the need for parenteral dispersed system pharmaceuticals is growing rapidly. This book serves as a current in-depth text for the design and manufacturing of parenteral dispersed systems. The fundamental physicochemical and biopharmaceutical principles governing dispersed systems are covered together with design, processing, product performance, characterization, quality assurance, and regulatory concerns. A unique and critically important element of this work is the inclusion of practical case studies together with didactic discussions. This approach allows the illustration of the application of dispersed systems technology to current formulation and processing problems and, therefore, this will be a useful reference text for industrial research and development scientists and will help them in making choices of appropriate dosage forms and consequent formulation strategies for these dosage forms. Quality control and

assurance as well as regulatory aspects that are essential to parenteral dispersed system product development are discussed in detail. This book also tackles current issues of in vitro testing of controlled release parenterals as well as the development of in vitro and in vivo relationships for these dosage forms.

This work is equally relevant to industrial and academic pharmaceutical scientists. The text is written in a way that the different chapters and case studies can be read independently, although the reader is often referred to other sections of the book for more in-depth information on specific topics. The case studies provide the reader with real problems that have been faced and solved by pharmaceutical scientists and serve as excellent examples for industrial scientists as well as for academics. This text will not only serve as a practical guide for pharmaceutical scientists involved in the research and development of parenteral dosage forms, but will also be a resource for scientists new to this field. The fundamental aspects together with the practical case studies make this an excellent textbook for graduate education.

The book is laid out as follows: Section (I) Basic Principles; Section (II) Dosage Forms; Section (III) Case Studies; and Section (IV) Quality Assurance and Regulation. The basic principles section includes physicochemical and biopharmaceutical principles, characterization and analysis and in vitro and in vivo release testing and correlation of in vitro and in vivo release data. The dosage forms covered in Section II are suspensions, emulsions, liposomes, and microspheres. These chapters detail design and manufacturing and a rationale for selection as well as any specific considerations for the individual parenteral dosage forms. Some formulation and processing aspects are common to all dosage forms and these are discussed in the basic principles chapters or the reader is referred to the appropriate chapter or case study. The dosage form chapters are followed by a case study section where nine case studies are presented that address: biopharmaceutical aspects of controlled release parenteral dosage forms; liposome formulation, design and product development; emulsion formulation, scale up and sterilization; microspheres

formulation and processing as well as microsphere in vitro and in vivo release studies; and development and scale up of a nanocrystalline suspension. The final section of the book covers quality assurance and regulatory aspects as well as an FDA perspective.

Diane J. Burgess

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