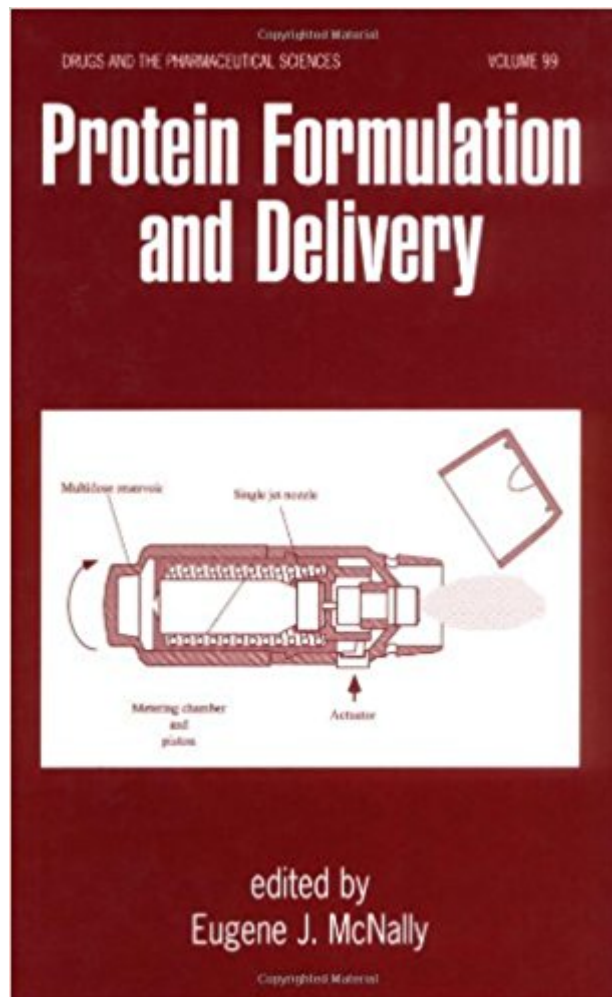


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Protein Formulation And Delivery (Drugs And The Pharmaceutical Sciences)



Synopsis

This handy reference provides insight into the approach used to identify the stability profile of a molecule that comes at the end of the drug registration process, and supplies an in-depth review of the mechanisms and associated causes of protein instability likely to be encountered during drug formulation development. Emphasizes the importance of selecting formulation conditions, excipients, and container closure systems to minimize degradation processes and maximize shelf stability! Organized to direct scientists new to the field of protein formulation to appropriate starting points of drug development, Protein Formulation and Delivery includes a discussion of accelerated stability testing and its limitations in identifying stable formulations details analytical methods commonly used in stability assessment and formulation development stresses the importance of demonstrating the stability-indicating nature of an assay describes the drug substance manufacturing process succinctly examines preformulation and development of traditional solution and lyophilized formulations intended for intravenous administration covers aseptic processing in drug development and the potential development of a freeze-drying cycle explores the development of nontraditional formulations, alternate routes of drug delivery, and controlled release dosage forms discusses the physical and chemical characteristics of proteins in microsphere delivery systems analyzes protein degradation mechanisms, and methods of detecting and monitoring degradation explores formulations intended for injection, inhalation, and controlled delivery and more! Presenting over 660 references and an extensive literature review valuable to scientists at every level, Protein Formulation and Delivery is an indispensable guide for industrial, research, and clinical pharmaceutical scientists, pharmacists, and pharmacologists; drug regulatory affairs personnel; biotechnologists; formulation, analytical, and synthetic chemists and engineers; and upper-level undergraduate and graduate students in these disciplines.

Book Information

Series: Drugs and the Pharmaceutical Sciences (Book 175)

Hardcover: 278 pages

Publisher: CRC Press; 1 edition (September 21, 1999)

Language: English

ISBN-10: 0824778839

ISBN-13: 978-0824778835

Product Dimensions: 9.3 x 6 x 0.7 inches

Shipping Weight: 15.2 ounces

Average Customer Review: Be the first to review this item

Best Sellers Rank: #5,901,716 in Books (See Top 100 in Books) #68 in Books > Medical Books > Pharmacology > Drug Delivery Systems #3253 in Books > Textbooks > Medicine & Health Sciences > Allied Health Services > Pharmacy #4916 in Books > Textbooks > Medicine & Health Sciences > Medicine > Basic Sciences > Pharmacology

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