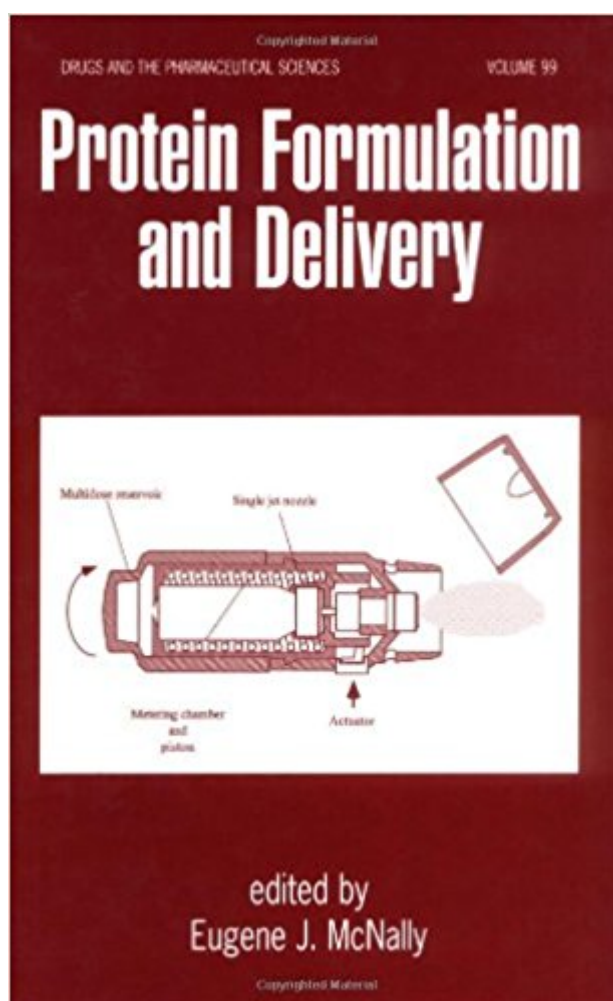




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Protein Formulation And Delivery (Drugs And The Pharmaceutical Sciences)



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.

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...written to assist the pharmaceutical scientist involved in the protein formulation and delivery processes...also...of use to students doing thesis research in these areas. Of particular value...are numerous insights into critical practical issues that impact the development of protein therapeutic products.- Pharmaceutical Research…concerns very timely topics….…well written and organized.-Pharmaceutical Research…concise and informative...…the authors have wisely chosen to illustrate their information with real-life examples and case studies.-Pharmaceutical Development and Technology…the most pertinent and readable summary of the familial ataxias that has been written to date.…an excellent summary of all the knowledge an interested clinician in this area needs to know.-European Journal of Paediatric Neurology…a 'must read'….exceptionally well written…..Highly recommended.-Journal of Controlled Release

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