

Rational Design of Stable Protein Formulations

By Carpenter, John F. / Manning, Mark C.

Book Condition: New. Publisher/Verlag: Springer, Berlin | Theory and Practice | Recombinant proteins and polypeptides continue to be the most important class of biotechnology-derived agents in today's pharmaceutical industry. Over the past few years, our fundamental understanding of how proteins degrade and how stabilizing agents work has made it possible to approach formulation of protein pharmaceuticals from a much more rational point of view. This book describes the current level of understanding of protein instability and the strategies for stabilizing proteins under a variety of stressful conditions. | 1 Practical Approaches to Protein Formulation Development.- Preparation for Formulation Development.- Resource Requirements for Formulation Development.- Useful Information for Designing Formulations.- Preformulation Development.-Characterization of Protein Pharmaceuticals.- Accelerated Stability Studies.- Development of Analytical Methods.- Evaluation of the Significance of Problems.- Formulation Development.-Formulation Options for Protein Pharmaceuticals.- Typical Protein Stability Problems: Causes and Solutions.- Optimization of Formulation Variables.- Necessary Studies for Formulation Development.- Strategies to Overcome Difficult Formulation Problems.- Formulation in Commercial Product Development.- Critical Formulation Decisions During Pharmaceutical Development.-Formulation for Early Preclinical and Clinical Studies.- Commercial Formulation.- Regulatory Issues in Formulation Development.- Appendix: List of Regulatory Documents.- References.- 2 Recombinant Production of Native Proteins from Escherichia coli.- Distribution of Expressed Proteins.- Cell...



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