

Mastering Method Development:

A Comprehensive Guide to
Sampling Protocols and
Robust CCI Testing



Cci Testing Guide

**Claudia Parvanta, David E.
Nelson, Richard N. Harner**



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Parenteral Medications, Fourth Edition Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration Key Features Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies The book is divided into seven sections Section 1 Parenteral Drug Administration and Delivery Devices Section 2 Formulation Design and Development Section 3 Specialized Drug Delivery Systems Section 4 Primary Packaging and Container Closure Integrity Section 5 Facility Design and Environmental Control Section 6 Sterilization and Pharmaceutical Processing Section 7 Quality Testing and Regulatory Requirements

Sterile Product Development Parag Kolhe, Mrinal Shah, Nitin Rathore, 2013-10-12 This comprehensive book encompasses various facets of sterile product development Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book Formulation approaches that discuss a variety of dosage forms including protein therapeutics lipid based controlled delivery systems PEGylated biotherapeutics nasal dosage form and vaccines Process container closure and delivery considerations including freeze thaw process challenges best practices for technology transfer to enable commercial product development innovations and advancement in aseptic fill finish operations approaches to manufacturing lyophilized parenteral products pen auto injector delivery devices and associated container closure integrity testing hurdles for sterile product closures Regulatory and quality aspects in the areas of particulate matter and appearance evaluation sterile filtration admixture compatibility considerations sterilization process considerations microbial contamination investigations and validation of rapid microbiological methods and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development

Challenges in Protein Product Development Nicholas W. Warne, Hanns-Christian Mahler, 2018-06-20 In this volume the authors discuss the many significant challenges currently faced in biotechnology dosage form development providing guidance shared experience and thoughtful reflection on how

best to address these potential concerns As the field of therapeutic recombinant therapeutic proteins enters its fourth decade and the market for biopharmaceuticals becomes increasingly competitive companies are increasingly dedicating resources to develop innovative biopharmaceuticals to address unmet medical needs Often the pharmaceutical development scientist is encountering challenging pharmaceutical properties of a given protein or by the demands placed on the product by stability manufacturing and preclinical or clinical expectations as well as the evolving regulatory expectations and landscape Further there have been new findings that require close assessment as for example those related to excipient quality processing viscosity and device compatibility and administration solubility and opalescence and container closure selection The literature varies widely in its discussion of these critical elements and consensus does not exist This topic is receiving a great deal of attention within the biotechnology industry as well as with academic researchers and regulatory agencies globally Therefore this book is of interest for business leaders researchers formulation and process development scientists analytical scientists QA and QC officers regulatory staff manufacturing leaders and regulators active in the pharmaceutical and biotech industry and expert reviewers in regulatory agencies

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