



THE CLEANING VALIDATION | CHAPTER 17 |

May 19, 2024

Reference Guidelines: ISPE | APIC | PDA | EMA

ESTABLISHING PROCESS PARAMETERS FOR A MANUAL CLEANING PROCESS



The purpose of this case study is to define appropriate parameters for manual cleaning of various equipment parts, utensils, and tools routinely used throughout manufacturing operations.

PARTS & TOOLS TO BE CLEANED:

- Scoops
- Spatulas
- Vessel with lid used in coating solutions
- Impeller blades
- Shaft
- Punches & Dies
- Hopper & lid

The wash room in the production area is designed with one -way flow: "dirty in" moving to "clean out", and is equipped with:

- Potable water line
- Pressurized hot potable water spray line.
- Sonicator
- Purified water spray line
- Clean dry compressed air line
- Heated drying rack area
- Timer
- In addition, there is an area where clean dry parts can be wrapped and labeled prior to being moved to the clean equipment storage area.

CLEANING PROCESS FOR TOOLS & SMALL PARTS:

- Removal of residue through mechanical force
- Sonication step
- Cleaning solution wash (Alkaline)
- Potable water rinse (to remove cleaning solution)
- Purified water final rinse
- Drying
- Visual Inspection
- Storing cleaned items

Cleaning Validation Manual

Priscilla Browne



Cleaning Validation Manual:

Cleaning Validation Manual Syed Imtiaz Haider, 2010-05-24 During the past decades enormous progress and enhancement of pharmaceutical manufacturing equipment and its use have been made And while there are support documents books articles and online resources available on the principles of cleaning and associated processing techniques none of them provides a single database with convenient ready to use training tools Until now Cleaning Validation Manual A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries elucidates how to train the man power involved in development manufacturing auditing and validation of bio pharmaceuticals on a pilot scale leading to scale up production With over 20 easy to use template protocols for cleaning validation of extensively used equipments this book provides technical solutions to assist in fulfilling the training needs of finished pharmaceutical manufacturers Drawing on the authors more than two decades of experience in the pharmaceutical and biotech industries the text offers hands on training based on current approaches and techniques The book does not merely provide guidelines or thought processes rather it gives ready to use formulas to develop Master Plan SOPs and validation protocols It includes cleaning procedures for the most commonly used equipment in various manufacturing areas and their sampling points using a pharmaceutical manufacturing site with both sterile and non sterile operations as the case facility It also provides the training guidelines on downloadable resources to enable users to amend or adopt them as necessary Grounded in practicality the book s applicability and accessibility set it apart It can be used as a guide for implementing a cleaning validation program on site without the help of external consultants making it a resource that will not be found collecting dust on a shelf but rather referred to again and again

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 **Quality Control Training Manual** Syed Imtiaz Haider, Syed Erfan Asif, 2016-04-19 Written to help companies comply with GMP GLP and validation requirements imposed by the FDA and regulatory bodies worldwide Quality Control Training Manual Comprehensive Training Guide for API Finished Pharmaceutical and Biotechnologies Laboratories presents cost effective training courses that cover how to apply advances in the life sciences to produce commercially viable biotech products and services in terms of quality safety and efficacy This book and its accompanying downloadable resources comprise detailed text summaries test papers and answers to test papers providing an administrative solution for management Provides the FDA Health Canada WHO and EMEA guidelines directly applicable to pharmaceutical laboratory related issues Offers generic formats and styles that can be customized to any organization and help management build quality into routine operations to comply with regulatory requirements Contains ready to use training courses that supply a good source of training material for experienced and inexperienced practitioners in the biotechnology biopharmaceutical industries Includes downloadable resources with downloadable training courses that can be adopted and directly customized to a particular organization Supplies ready to use test papers that allow end users to record all raw data up to the issuance of the attached certificate The biotechnology bioscience industries are regulated worldwide to be in compliance with cGMP and GLP principles with particular focus on safety issues Each company must create a definite training matrix of its employees The training procedures in this book enable end users to understand the principles and elements of manufacturing techniques and provide documentation language ranging from the generic to the specific The training courses on the downloadable resources supply valuable tools for developing training matrices to achieve FDA Health Canada EMEA MHRA UK WHO and GLP compliance Pharmaceutical Vendors Approval Manual Erfan Syed Asif, 2021-12-12 This book provides stepwise guidance on how to evaluate audit qualify and approve an active pharmaceutical ingredient API and packaging material manufacturer and supplier to enhance the GMP within the industry The book will also be beneficial for institutions conducting pharmaceutical technology courses in terms of GMP and GLP applications The Pharmaceutical Vendors Approval Manual provides readers and front line health care products manufacturers R D management and biotech laboratories all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements This book provides a simple concise and easy to use reference tool covering basic quality concepts and the elements of vendor s assessment qualification and approval required by the pharmaceutical educational institutions and professional certification bodies It is equally relevant to Quality Assurance officers Quality Control Analysts Quality Auditors and other personnel involved in GMP GLP services in the company The book will also be beneficial for the institutions conducting Pharmaceutical technology study courses in terms of GMP and GLP applications This book provides readers and front line health care products manufacturers R D management and biotech

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GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 2 - Regulations, Standards, and Guidelines) Leonard Steinborn,2004-12-30 This well known QA manual has been updated to provide the guidance readers need to assess their compliance with standard regulations This Volume 2 of a three part package contains the full text on FDA regulations EC and IPEC guidelines ISO BSI standards referenced in the checklists furnished in volume 1 Easy to read and organized to provide fa

Cleaning Validation Priscilla Browne,2017-08-10 This paperback book provides an introduction to Cleaning Verification and Validation for pharmaceutical and biological equipment and facilities It provides a practical framework for the design and execution of cleaning validation Cleaning Validation is a regulatory requirement as per GMP There are many organisations and bodies which provide guidance of implementing a Cleaning Program such as PIC s ICH PDA reports EU GMP V4 to name a few The key elements to achieving a successful cleaning validation include 1 understanding the sources of residues soils excipients actives microbes etc 2 developing a cleaning procedure 3 developing a test method 4 validating the cleaning procedure in respect of the products and equipment to be used in manufacturing

Summary of title index Introduction What is Cleaning Why Clean Verification and Validation Definitions Regulatory Requirements FDA EU GMP ICH Q7 Validation Standards Stages of Validation Stage 1 Process Design Stage 2 Process Qualification Stage 3 Continued Process Verification Validation General Principles and Practices Cleaning Validation Prerequisites to Cleaning Validation Execution Validation Report Clean In Place CIP Visibly Clean Soils and their behaviour Detergents Validation Strategies Summary How are Acceptance levels defined Historical Context of Limits Uses of the term limit PDA Technical Report No 29 Calculation of MACO MACO for each piece of equipment Cleaning Validation Protocol PIC S Guidance on Limits Test Methods ICH Q7 Validation of Analytical Methods Definitions Cleaning Process Design Equipment Considerations Cleaning Agent Approval Critical Cleaning Parameters Cleaning Pipes Dead Legs Connections and Tie ins Valves Materials of Construction Pressure Testing Sampling Direct Sampling Rinse Sampling Sources of Contaminants Utilities Introduction Key Definitions Compressed Air Water Systems Clean Steam Useful References Appendix Precision Cleaning Medical Devices

Pharmaceutical Production Bill Bennett,Graham Cole,2003 This title is a general introduction aimed at all those involved in the engineering stages required

for the manufacture of the active ingredient and its dosage forms Biotechnology Operations Michael J. Roy, 2011-06-27 Because of rapid developments in the biotechnology industry and the wide range of disciplines that contribute to its collective growth there is a heightened need to more carefully plan and fully integrate biotech development projects Despite the wealth of operations experience and associated literature available no single book has yet offered a comprehensive practical guide to fundamentals Filling the void Biotechnology Operations Principles and Practices reflects this integrative philosophy serving as a practical guide for students professionals or anyone else with interests in the biotech industry Although many books emphasize specific technical aspects of biotech this is perhaps the first to integrate essential concepts of product development and scientific and management skills with the seven functional areas of biotechnology Biomanufacturing Clinical trials Nonclinical studies Project management Quality assurance Quality control Regulatory affairs A practical roadmap to optimizing biotechnology operations this reference illustrates how to use specific product planning design and project management processes to seamlessly merge plans and efforts in the key functional areas Applying lessons learned throughout the nascent history of biotech author Michael Roy highlights developmental principles that could bring future products to market more safely and efficiently Drawing from his experiences working in industry and teaching a graduate course at the University of Wisconsin this hotly anticipated book clarifies basic methodologies and practices to help reduce risks and resolve problems as future technological discoveries are developed into tangible products

Pharmaceutical Dosage Forms Herbert Lieberman, 1998-02-25 This third volume of the second edition offers information on specialized products such as emulsions liposomes polymers and polymeric pharmaceutical excipients It explains the requirements for conducting clinical research and obtaining marketing approval for new drug products

Developments in Surface Contamination and Cleaning, Volume 7 Rajiv Kohli, Kashmiri L. Mittal, 2014-11-18 As device sizes in the semiconductor industries are shrinking they become more vulnerable to smaller contaminant particles and most conventional cleaning techniques employed in the industry are not as effective at smaller scales The book series Developments in Surface Contamination and Cleaning as a whole provides an excellent source of information on these alternative cleaning techniques as well as methods for characterization and validation of surface contamination Each volume has a particular topical focus covering the key techniques and recent developments in the area The chapters in this Volume address the sources of surface contaminants and various methods for their collection and characterization as well as methods for cleanliness validation Regulatory aspects of cleaning are also covered The collection of topics in this book is unique and complements other volumes in this series Edited by the leading experts in small scale particle surface contamination cleaning and cleaning control these books will be an invaluable reference for researchers and engineers in R D manufacturing quality control and procurement specification situated in a multitude of industries such as aerospace automotive biomedical defense energy manufacturing microelectronics optics and xerography Provides a state of the art survey and best practice guidance

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Table of Contents Cleaning Validation Manual

1. Understanding the eBook Cleaning Validation Manual
 - The Rise of Digital Reading Cleaning Validation Manual
 - Advantages of eBooks Over Traditional Books
2. Identifying Cleaning Validation Manual
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Cleaning Validation Manual
 - User-Friendly Interface
4. Exploring eBook Recommendations from Cleaning Validation Manual
 - Personalized Recommendations

- Cleaning Validation Manual User Reviews and Ratings
- Cleaning Validation Manual and Bestseller Lists
- 5. Accessing Cleaning Validation Manual Free and Paid eBooks
 - Cleaning Validation Manual Public Domain eBooks
 - Cleaning Validation Manual eBook Subscription Services
 - Cleaning Validation Manual Budget-Friendly Options
- 6. Navigating Cleaning Validation Manual eBook Formats
 - ePub, PDF, MOBI, and More
 - Cleaning Validation Manual Compatibility with Devices
 - Cleaning Validation Manual Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Cleaning Validation Manual
 - Highlighting and Note-Taking Cleaning Validation Manual
 - Interactive Elements Cleaning Validation Manual
- 8. Staying Engaged with Cleaning Validation Manual
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Cleaning Validation Manual
- 9. Balancing eBooks and Physical Books Cleaning Validation Manual
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Cleaning Validation Manual
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Cleaning Validation Manual
 - Setting Reading Goals Cleaning Validation Manual
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Cleaning Validation Manual
 - Fact-Checking eBook Content of Cleaning Validation Manual

- Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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