

THE CLEANING VALIDATION | CHAPTER 17 |

May 19, 2024

Reference Guidelines: ISPE | APIC | PDA | EMA

ESTABLISHING PROCESS PARAMETERS FOR A MANUAL CLEANING PROCESSS

PARAMETERS FOR THE CLEANING SEQUENCE		
STEP	PURPOSE	PARAMETERS
SOAKING	Wet the product adhered to equipment reduce scrubbing time	Soaking Time = Minimum 10 min
SONICATION	Loosen particles and compacted product from surfaces	Sonication time = Minimum 10 min Sonification frequency = Medium
SCRUBBING	Mechanical action to remove product from surfaces	Scrubbing duration = Minimum 1 min
ALKALINE WASH	Dissolve any remaining product from equipment surfaces	Solution concentration = 10% Wash time = Minimum 10 min
POTABLE WATER RINSE	Remove alkaline solution	Rinse Time = Minimum 2 min Rinse Pressure = 10 psig
PURIFIED WATER FINAL RINSE	Apply final rinse using Purified Water	Rinse Time = Minimum 30 sec Rinse Pressure = 10 psig
DRYING	Remove water from tools and parts surfaces Reduce proliferation of microorganisms	Drying time = minimum 30 min Finish with dry wipe
VISUAL INSPECTIONSTORAGE	Verify surfaces	Light Lumens = > 200 lux at inspection level
STORAGE	Apply identification and protect tools and parts from environment to keep them cleaned until use	None

Cleaning Validation Manual

Erfan Syed Asif, Shahid Bader Usmani

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 GMP Compliance, Productivity, and Quality Vinay Bhatt, 1998-06-30 Written by twenty eight experts filled with recommendations that can immediately be put into action this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost effective regulatory compliance Drawn from name brand and generic companies and regulatory and contract organizations across the globe the contributing authors bring readers a combined 450 years of hands on experience They offer thought provoking questions to help readers diagnose their company's challenges needs and available options all with the single purpose of achieving their ultimate goals quality high productivity and profitability 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 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 covers basic quality concepts and the elements of vendor's assessment qualification and approval required by the pharmaceutical educational institutions and professional certification bodies provides stepwise guidance on how to evaluate audit qualify and approve an API and packaging material manufacturer and supplier to enhance the GMP within the industry provides ready to use regulatory documentation e g letter of commitment questionnaire SOP etc required for API and Packaging Materials contract Provided material can be easily tailored to incorporate changes to add in house vendor's qualification requirements Erfan Syed Asif Ph D is a Senior Consultant at PharmEng Technology 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 1Easy to read and organized to provide fa **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 manufacturr of the active ingredient and its dosage forms 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 for scientists and engineers engaged in surface cleaning or handling the consequences of surface contamination Addresses the continuing trends of shrinking device size and contamination vulnerability in a range of industries spearheaded by the semiconductor industry and others Includes new regulatory aspects Infection Control in the Dental Office Louis G. DePaola, Leslie E. Grant, 2019-11-17 This book reviews the principles of infection control and the guidelines and standards of care in multiple countries discussing them within the context of the practice of dentistry. The aim is to enable dental practitioners to ensure that the appropriate measures are adopted for each patient contact thereby minimizing the risk of transmission of infection a goal that is becoming ever more important given the threats posed by new or re emerging infectious diseases and drug resistant infections Readers will find information and guidance on all aspects of infection control within the dental office hand and respiratory hygiene use of personal protective equipment safe handling of sharps and safe injection practices management of occupational exposures maintenance of dental unit water quality surface disinfection and the cleaning and sterilization of dental instruments Infection Control in the Dental Office will be an invaluable asset for all dental practitioners including dentists dental specialists dental hygienists and dental assistants **Validation** Jon Voss, 2018-05-04 This book is intended to serve as a source of practical technical information for those persons in the biotechnology industry Casestudies and or actual industry examples are used to support the textwherever possible While much of the material contained within thistext is equally applicable to nonbiopharmaceutical processes the emphasis has been focused directly upon biopharmaceutical manufacturing Section I provides an in depth analysis of the design concepts that lead to cleanable equipment Also covered in the tirst section are cleaning mechanisms and cleaning systems The first section is particularly useful to those persons faced with the task of designing systems that will be cleaned and also provides the biochemicaloockground of the mechanisms associated with the removal of commonbiotechnology soils Section II focuses on cleaning validation concepts While thematerial is equally useful for single product cleaning emphasis isplaced upon multiproduct cleaning validation Included in Section II are general validation principles as thex apply to cleaning validation detailed analysis of cleaning process validation sampling techniques analytical methods and acceptance criteria The material in this sectionwill be useful to anyone responsible for the development of a cleaning validation program The final section Section III provides an overview of multiproductbiotechnology manufacturing procedures Included in this section is ananalysis of the risk to benefit scenarios associated with the various formsof product manufacturing analysis of changeover programs uipmentconsiderations and material transfer systems as they are affected bymultiproduct manufacturing strategies Biotechnology Operations John M. Centanni, Michael J. Roy, 2016-09-19 This book describes seven areas in the field of biotechnology operations as practiced by biopharmaceutical firms and nonprofit institutions

Revisions focus upon changes that have occurred in several areas over the past six years with emphasis on regulatory biomanufacturing clinical and technical information along with processes and guidlines that have added to the discipline Examples are increased for new technical fields such as cell and tissue engineering Further illustrations or figures are added to each chapter to emphasize particular points **Infection Control in the Dental Office in the Era of COVID-19** Louis G. DePaola, Robert Windsor, Nisha Ganesh, 2024-10-14 This book discusses the treatment of dental patients in the post COVID pandemic years and the required compliance with recommended infection control practices to ensure the safe delivery of oral health care The COVID 19 pandemic has had the most dramatic impact on healthcare inclusive of dentistry in history SARS CoV 2 the virus that causes COVID 19 is a very dynamic virus and each new variant appears to be more transmissible than previous variants More effective infection control strategies had to be developed to prevent transmission of COVID 19 in the dental office Readers will find guidance on the reduction of aerosol in the dental office information on vaccines vaccinations and the re emergence of vaccine preventable diseases Infection control during implant placement oral surgical procedures N2O administration and IV sedation is explained In addition to SARS CoV 2 the book provides information on other emerging respiratory diseases such as Influenza Respiratory Syncytial Virus RSV and the emergence of Vaccine Preventable Diseases Measles Mumps Rubella Polio HPV that present significant risk of transmission if proper infection control practices are not followed The indirect effects of the COVID 19 pandemic are discussed including a significant increase of STDs syphilis gonorrhea chlamydia herpes HPV new blood borne infections such as HIV HBV and HCV infections as well as a significant increase of healthcare acquired infections and superbugs 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 indexIntroduction 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 Basics of Pharmaceutical Manufacturing and Quality Operations Erfan Syed Asif, Shahid Bader Usmani, 2024-03-14 This book provides guidance on how to meet the requirements of the pharmaceutical industry as a beginner It includes procedures for production and packaging batch auditing as well as all quality measures used in the pharmaceutical industry This book also provides questions and answers with each chapter for institutes and trainers providing basic training to the new graduates and new comers to the industry Basics of Pharmaceutical Manufacturing and Quality Operations A Comprehensive Guide is primarily written for anyone in the pharmaceutical industry interested in development and manufacturing of active pharmaceutical ingredient API and finished pharmaceutical manufacturers in both sterile and non sterile areas The book is a simple concise and easy to use reference tool covering basic quality concepts required by the pharmaceutical educational institutions and professional certification bodies It describes details of all GXP activities that are directly related to Quality Safety and Efficacy of the products manufactured under the umbrella of Quality Operations common testing methods which are used in any modern industry Requirements of Validation and Qualification of equipment facilities and processes integral segments of Drug product manufacturing storage and distribution practices. The material provides stepwise guidance on how to evaluate audit qualify and approve a pharmaceutical product to enhance the GMP within the industry The book is written with the idea of providing basic knowledge to undergraduate students who are preparing to enter the industry at the end of their graduation The book would also be beneficial for institutions conducting pharmaceutical technology study courses in terms of GMP and GLP applications Features Provides readers and front line health care product manufacturers 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 Provides stepwise guidance on how to evaluate audit qualify and approve a pharmaceutical product and packaging material to enhance the GMP within the industry Includes significant processes and steps in production for all common dosage forms Explains how in process and finished products are released Provides an ideal and effective tool for anyone starting Quality Assurance Quality control Production responsibilities Block's Disinfection, Sterilization, and Preservation Gerald McDonnell, 2020-06-26 With more international contributors than ever before Block s Disinfection Sterilization and Preservation 6th Edition is the first new edition in nearly 20 years of the definitive technical manual for anyone involved in physical and chemical disinfection and sterilization methods. The book focuses on disease prevention rather than eradication and has been thoroughly updated with new information based on recent advances in the field and understanding of the risks the technologies available and the regulatory environments Cleaning Validation Manual Sved

Imtiaz Haider, 2019-12-31 This will be a substantial revision of a well regarded work in the biopharmaceutical area that supplies a basic education of cleaning validation Each chapter will be updated with major emphasis put on microbiological cleaning of equipment surfaces protocols for encapsulation machines and manufacturing vessels. There will also be extensive coverage on WHO World Health Organization good manufacturing guidelines for clean validation standards The author is also proposing the inclusion of specific case studies related to appropriate chapters where the author's own technical experience in these matters will be illustrated Pharmaceutical Production Facilities Graham Cole, 1998-02-11 Pharmaceutical Production Facilities Design and Applications considers the concepts and constraints that have to be considered in the design of small medium and large scale production plants The layout along with the flow of materials and personnel through facilities are considered with reference to ensuring compliance with current good manufac Ng,2015-04-13 The third edition of this best selling book continues to offer a user friendly step by step introduction to all the key processes involved in bringing a drug to the market including the performance of pre clinical studies the conduct of human clinical trials regulatory controls and even the manufacturing processes for pharmaceutical products Concise and easy to read Drugs From Discovery to Approval Third Edition guickly introduces basic concepts then moves on to discuss target selection and the drug discovery process for both small and large molecular drugs The third edition incorporates the latest developments and updates in the pharmaceutical community provides more comprehensive coverage of topics and includes more materials and case studies suited to college and university use Biotechnology is a dynamic field with changes across R D clinical trials manufacturing and regulatory processes and the third edition of the text provides timely updates for those in this rapidly growing field Quality Operations Procedures for Pharmaceutical, API, and Biotechnology Syed Imtiaz Haider, Erfan Syed Asif, 2012-06-06 To stay in compliance with regulations pharmaceutical medical and biotech companies must create qualtiy SOPs that build in the regulatory requirements into actions and describe personal flow internal flow flow of information and processing steps Quality Operations Procedures for Pharmaceutical API and Biotechnology and the accompanying CD Pharmaceutical Microbiological Quality Assurance and Control David Roesti, Marcel Goverde, 2020-01-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks

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