

GMP Standard Operating Procedures

Quality Management SOPs

QMS-005 Preparation of Standard Operating Procedure
QMS-010 Classification, Definition and Approval Matrix of GMP Documents
QMS-015 Quality Documentation Management and Change Control Procedure
QMS-020 Documentation Rule for GMP Documents
QMS-025 Control, Tracking and Distribution Management of GMP Documents
QMS-030 Preparation, Maintenance and Change Control of Master Documents
QMS-035 Pharmaceutical Deviation Investigation Procedure
QMS-040 Determination of Shelf Life of Product
QMS-045 External Supplier Selection and Evaluation Procedure
QMS-050 External Supplier Certification Procedure
QMS-055 Pharmaceutical Product Complaint Procedure
QMS-060 Annual Product Review for Medicinal Products
QMS-065 Manufacturing Rework Reprocessing Procedure
QMS-070 Responsibility of Authorized Person
QMS-075 Procedure for Product Identification and Traceability
QMS-080 Procedure and Preparation of GMP Audits
QMS-085 Batch Documentation Checklist for Release for Sale
QMS-090 Evaluation of Batch Documentation and Release for Sale Process
QMS-095 GMP Training Procedure
QMS-100 Preparation and Maintenance of GMP Training Materials
QMS-105 House Keeping Audit Procedure of GMP Facility
QMS-110 Management and Control of Contract Work
QMS-115 Sourcing of Raw Materials, Components & Imported Finished Goods
QMS-120 Quality Concern Investigation Process
QMS-125 Change Management System
QMS-130 Cross Functional Investigation

Quality Templates

TEMPLATE-005 Raw Material Specification and Test Report Template
TEMPLATE-080 Internal Audit Report Template
TEMPLATE-085 Training Report Template
TEMPLATE-090 Form Template
TEMPLATE-095 SOP Template
TEMPLATE-100 Quality Assurance Agreement Template
TEMPLATE-105 Third Party Manufacture Dispatch Report Template
TEMPLATE-110 In-House Manual Template
TEMPLATE-115 Rework Protocol for Manufactured Finished Goods

GMP Standard Operating Procedures

TEMPLATE-120 Vendor Assurance and Audit Report Template
TEMPLATE-125 Rework Protocol for Work in Progress Goods
TEMPLATE-130 Position Paper Template
TEMPLATE-135 Laboratory Control Method Template
TEMPLATE-140 Product Formulation Template
TEMPLATE-145 Finished Product Specification and Test Report Template
TEMPLATE-150 Packaging Material Specification and Test Report
TEMPLATE-155 Bill of Materials Template

Audit Preparation Manuals

Audit - 01 Auditing Principles for GMP Audit
Audit - 02 Understanding Worldwide Regulatory Requirements
Audit - 03 Personnel & Training System Audit
Audit - 04 Deviation Management System Audit
Audit - 05 Validation System Audit
Audit - 06 Change Management System Audit
Audit - 07 Complaint System Audit
Audit - 08 Documentation System Audit
Audit - 09 Calibration, Preventative Maintenance & Housekeeping System Audit
Audit - 10 Computerized Systems Audit
Audit - 11 Utility Systems Audit
Audit - 12 Warehouse and Distribution System Audit
Audit - 13 Environmental Monitoring System Audit
Audit - 14 Microbiology and Sterility Testing Laboratory Audit
Audit - 15 Analytical Quality & Stability Testing Laboratory Audit
Audit - 16 Material Handling System Audit
Audit - 17 Active API Manufacturer Audit
Audit - 18 Packaging Material Supplier Audit
Audit - 19 Auditing a Packaging and Labeling Operation
Audit - 20 Auditing an Aseptic Sterile Area
Audit - 21 Auditing an Excipient Supplier
Audit - 22 Auditing an Oral Solid Solution Area

Validation SOPs

VAL-005 Concept and Procedure of Validation for GMP Facility
VAL-010 Revalidation Procedure of a GMP Facility
VAL-015 Laboratory Methodology Validation Procedure
VAL-020 Equipment Cleaning Validation Procedure
VAL-025 Validation Activities of Laboratory Instruments

GMP Standard Operating Procedures

VAL-030 Equipment Specification and Qualification Procedure

VAL-035 In-House Trial Procedure

VAL-040 Computerized Systems Validation

VAL-045 Impact Assessment for Computerized Systems

VAL-050 Functional Testing Guide for Computerized System

VAL-055 Guidelines for Design Qualification

VAL-060 Protecting Reliability of Electronic GMP Documents

Validation Templates

TEMPLATE-010 Cleaning Validation-Rinsing Test Template

TEMPLATE-015 Cleaning Validation-Swab Test Template

TEMPLATE-020 Cleaning Validation-Comparative Analysis Template

TEMPLATE-025 Example of Installation Qualification Report

TEMPLATE-030 Example of Operational Qualification Report

TEMPLATE-035 Example of Operational Qualification Test Protocol

TEMPLATE-040 Example of Performance Qualification Test Protocol

TEMPLATE-045 Example Product Quality Risk assessment

TEMPLATE-050 Example Validation File Index

TEMPLATE-055 Example of Validation Plan

TEMPLATE-060 Example of Validation Report

TEMPLATE-065 Example EHS Audit Report

TEMPLATE-070 Example of User Requirement Specification

TEMPLATE-160 Example of Commissioning Plan

TEMPLATE-165 Example of Design Qualification Protocol

TEMPLATE-170 Example of Installation Qualification Equipment

TEMPLATE-175 Example of Installation Qualification HVAC

TEMPLATE-180 Example of Installation Qualification Operating Environment

TEMPLATE-185 Example of Installation Qualification Pipe-work

TEMPLATE-190 Example of Installation Qualification Utilities

TEMPLATE-195 Example of Electrical Demand Specification

TEMPLATE-200 Example of Instrumentation Demand Specification

TEMPLATE-205 Example of Mechanical Demand Specification

TEMPLATE-210 Example of HAZOP Report

TEMPLATE-215 Example of Traceability Matrix Report

TEMPLATE-220 Example of Validation Discrepancy Form

TEMPLATE-225 Example of Validation Report Combined OQ_PQ

TEMPLATE-230 Example of Project Definition Report

TEMPLATE-235 Example of Project Evaluation and Closeout Report

TEMPLATE-240 Example of Test Protocol Change Request Form

GMP Standard Operating Procedures

TEMPLATE-245 Example of Installation Qualification Computer
TEMPLATE-250 Cleaning Validation Interim Report Template
TEMPLATE-255 Cleaning Validation Campaign Length Increase Protocol
TEMPLATE-260 Cleaning Validation Protocol Template
TEMPLATE-265 Cleaning Validation Report Template
TEMPLATE-270 Installation and Operational Qualification Protocol Template
TEMPLATE-275 Installation and Operational Qualification Report Template
TEMPLATE-280 Packaging Validation Protocol Template
TEMPLATE-285 Packaging Validation Report Template
TEMPLATE-290 Process Validation Protocol template
TEMPLATE-295 Process Validation Report Template
TEMPLATE-295 Process Validation Report Template-pdf links
TEMPLATE-300 Product Transfer Protocol Template
TEMPLATE-305 Electronic Records and Signatures Compliance Assessment
TEMPLATE-310 Impact Assessment Template for Equipment, Utility and Computer

QC Laboratory SOPs

LAB-005 Raw Materials Retest Dating and Frequency
LAB-010 Calibration Policies for Laboratory Instruments
LAB-015 Retention of Laboratory Documentation
LAB-020 Management of Reference Substances
LAB-025 Laboratory Workbook
LAB-030 Creation of Certificate of Analysis
LAB-035 Managing Analytical Reagents
LAB-040 Laboratory Waste Management
LAB-045 Retention Samples Management in Laboratory
LAB-050 Laboratory Supplier Approval
LAB-055 Investigation Procedure for Out of Specification Laboratory Results
LAB-060 Laboratory Testing and Documentation for Raw Materials
LAB-065 Laboratory Testing and Documentation of Finished Products
LAB-070 Preparation and Maintenance of Stability Protocols
LAB-075 Stability and Trial Testing Procedure for pharmaceutical Products
LAB-080 Preparation of Disinfectant solution IPA
LAB-085 Laboratory Analytical Determinations
LAB-090 HPLC Reproducibility, Column Performance and Testing Guidelines
LAB-095 HPLC Method Development & Validation Procedure
LAB-100 Laboratory In Process and Finished Product Quality Control

Micro Laboratory SOPs

GMP Standard Operating Procedures

MICLAB-005 Entry Procedure for Sterile Filling Areas
MICLAB-010 Validation of Aseptic Gowning Procedures
MICLAB-015 Microbiological Data Recording Procedure
MICLAB-020 Destruction of Biological Waste in Microbiology Laboratory
MICLAB-025 Depyrogenation of Glassware in Microbiology Laboratory Oven
MICLAB-030 Media Preparation in Microbiology Laboratory
MICLAB-035 Aseptic Media Filling and Microbiology Integrity Leak (Soup) Testing
MICLAB-040 Aseptic Media Filling and Soup Test Guideline
MICLAB-045 Environmental and Plant Hygiene Monitoring Procedure
MICLAB 050 Microbial Limit Testing Procedure by Using Laminar Flow Cabinets.
MICLAB-055 Microbiological Monitoring of Plant Water Systems
MICLAB-060 Micro Laboratory Procedure for Sterility Testing
MICLAB-065 Determination of Heat Resistance of Spore Forming Organisms
MICLAB-070 Identification of Microorganisms to Genus and Species Level
MICLAB-075 Micro Evaluation on Bioburden, Non sterile and Raw Materials
MICLAB-080 Bacterial EndoToxin Testing (LAL) - Gel Clot Method
MICLAB-085 Bacterial EndoToxin Testing kCA Method
MICLAB-090 Stock Suspensions of Micro Organisms
MICLAB-095 Sterile Sampling Procedure for Microbiology Laboratory
MICLAB 100 Microbiological Testing of Compressed Gasses
MICLAB-105 Gel Clot Validation Method
MICLAB-110 Investigation and Retest Procedure for Atypical and Out of Specification Results
MICLAB-115 Operation and Calibration of Sievers 820 TOC Analyser
MICLAB 120 IPA Contamination Testing Procedure
MICLAB 125 Control of Microbiology Test Methods
MICLAB 130 Handling of Test Sample in Microbiology Laboratory
MICLAB 135 Documentation Requirement for Micro Test Method Validation

Manufacturing and Packaging SOPs

MAN-005 Clothing Requirements Inside the Factory Area
MAN-010 Cleaning Responsibilities and Methods for Employees
MAN-015 Factory Cleaning Procedure
MAN-020 Manufacturing Pest Control Procedure
MAN-025 Tours of Factory
MAN-030 Management of Production Logbook
MAN-035 Examples of Packaging Configuration for Production Line
MAN-045 Checking Requirements of Components Prior to Use
MAN-050 Safety Tag Out Procedure
MAN-055 Procedures for Line Clearance, Line Opening and Line Cleaning

GMP Standard Operating Procedures

MAN-060 Reconciliation Procedure of Component and Product
MAN-065 Example-Operation of Barcode Reader
MAN-070 Example-IBC Operation and Cleaning
MAN-075 Example of a Tablet Packing Machine -Construction, Operation and Cleaning
MAN-080 Example of Manufacturing Instruction for Tablet Packing
MAN-085 Mop Cleaning Procedure
MAN-090 Scheduling of Production Lines
MAN-095 Vacuum Leak Testing Procedure for Finished Goods
MAN-100 Weighing Equipment - Checking and Calibration
MAN-110 Example of Operation of automatic Checkweigher for Finished Packs
MAN-115 Machine Start up Challenges and In-Process Testing Procedures
MAN-120 Finished Pack Sampling by Production Personnel

Warehouse Management SOPs

PUR-005 Material Purchasing Information Record and Source List
PUR-010 Generation of Purchase Order For Inventory and Consumables
WAR-005 Procedure for Receipt of Incoming Goods
WAR-010 Incoming Raw Materials and Components-Handling by QC Sampler
WAR-015 Warehouse Processing Issues, Returns and Rejects
WAR-020 Dispatch of Goods From Warehouse
WAR-025 Warehouse Inventory Management Procedure
WAR-030 Design of Warehouse Locations and Storage Area
WAR-040 Finished Goods Transfer to Quarantine and Distribution Warehouse
WAR-045 Sampling Procedure of Raw Materials
WAR-050 Sampling of Components and Printed Materials
WAR-055 Work in Progress Area
WAR-060 Safety Procedure of Warehouse Racking
WAR-065 Forklift Operation in Warehouse
WAR-075 Example of Tablet Dispensary Procedure
WAR-080 Example of Tablet Sampling Procedure as Raw Material

Environment, Health and Safety SOPs

EHS-005 Hazardous Chemical Substance Management
EHS-010 Environmental, Health and Safety Risk Management
EHS-015 Waste Removal Process
EHS-020 Identifying EHS Issues
EHS-025 EHS Incident Management Procedure
EHS-030 First Aid Procedure

GMP Standard Operating Procedures

Quality and Validation Guidance

- Guidance 001 - General Guidance for Analytical Test Method Validation
- Guidance 002 - Risk Assessment and Prioritization for Test Method Validation
- Guidance 003 - System Suitability for Analytical Test Method Validation
- Guidance 004 - Precision and Accuracy for Analytical Test Method Validation
- Guidance 005 - Quantitation and Detection Limit for Analytical Test Method Validation
- Guidance 006 - Linearity, Range and Specificity for Analytical Test Method Validation
- Guidance 007 - Robustness for Analytical Test Method Validation
- Guidance 008 - Residue Limits Calculation during Equipment Cleaning for medicinal products
- Guidance 009 - Swab Sampling Process and Visual Inspection Points for medicinal Equipment
- Guidance 010 - Grouping of Product and Equipment and How to Select Worst - Case Product
- Guidance 011 - Rinsate and Swab Sampling Process during Test Method Development and Validation
- Guidance 012 - Inspection and Quantitation Process in Cleaning Validation
- Guidance 013 - How to Investigating Unknown Peaks in Chromatography
- Guidance 014 Documentation and Instruction Records for Cleaning Activities
- Guidance 015 - How to Identify Critical Process Parameters for Medicinal Products
- Guidance 016 - How to Identify Critical Steps for Medicinal Product Process
- Guidance 017 - Process Validation for Medicinal Products and Medical Devices
- Guidance 018 - Equipment Cleaning Validation for API Processes
- Guidance 019 - Equivalence Criteria of Impurities for API Process Validation
- Guidance 020 - Equivalency Comparison of Medicinal Product Validation
- Guidance 021 - Establishing and Extending Clean Equipment Hold Times
- Guidance 022 - Evaluating Non-Cleaned Equipment Hold Times for Cleaning Validation
- Guidance 023 - Evaluation of Changes for Potential Impact on Process Validation
- Guidance 024 - General Guidance for Process Validation Sampling
- Guidance 025 - Swab & Visual Inspection Sampling Locations for Medicinal Products Equipment
- Guidance 026 - In-Process and Bulk Medicinal Product Holding Times
- Guidance 027 - Demonstration of Active Pharmaceutical Ingredient (API) Batch Homogeneity
- Guidance 028 - Documentation Example for Continuous Quality Verification
- Guidance 029 - Documentation Requirements to Support Continuous Quality Verification
- Guidance 030 - Selection Criteria of Dose & Toxicity Data for Use in Cleaning Limit Calculation
- Guidance 031 - Inspection Attributes in Packaging Validation of Non-Sterile Medicinal Products
- Guidance 032 - Guideline for Laboratory Equipment Qualification
- Guidance 033 - Concepts of Matrices and Bracketing in Process Validation
- Guidance 034 - Considerations for Selecting Packaging Lot Sizes during Packaging Validation
- Guidance 035 - Environmental Control for Non-Sterile API Manufacturing Area
- Guidance 036 - Critical Process Parameters and Validation Practices in Packaging Validation
- Guidance 037 - Process Validation Sampling for Non-Sterile Liquid, Semi Solid Medicinal Products
- Guidance 038 - Process Validation Sampling for Non-Sterile Solid Dose Medicinal Products

GMP Standard Operating Procedures

Guidance 039 - Performance Qualification versus Process Validation

Guidance 040 - Periodic Review of Processes and Systems

Guidance 041 - Release For Sale of Medicinal Product and API Pre-Validation & Validation Batches

Guidance 042 - Selection of Critical Process Parameters for Validation

Guidance 043 - Semi-Solid Dosage Forms-Critical Process Parameters

Guidance 044 - Solid Oral Dosage Forms-Potential Critical Process Parameters

Guidance 045 - Solvent Recovery Validation Example

Guidance 046 - Test Deviations during Validation

Guidance 047 - Validation Activities during Technology Transfers

Guidance 048 - Validation Considerations for Re-work and Re-process of API

Guidance 049 - Validation Documentation

Guidance 050 - Shipping Validation for Biopharmaceutical Materials

Guidance 051 - System Level Impact Assessment for Information Systems

Guidance 052 - Clean Pure Steam System Commissioning and Qualification

Guidance 060 - Product Quality Complaint Handling

Guidance 061 - Application of Quality Risk Management to Periodic Review of SOPs

Guidance 062 - Statistical Rationale for Raw Material Sampling

Guidance 063 - Quality Risk Management Application Critical Instrument Calibration

Guidance 064 - Structured On-the-Job Training System

Guidance 065 - Training system for Aseptic and Preparation for Aseptic Operators and Support Staff

Guidance 066 - Disposal of Rejected and Waste Materials

Guidance 067 - Quality Assurance Audits

Guidance 068 - Status Indication of Materials and Inventories

Guidance 069 - Annual Product Records Review

Guidance 070 - Receipt, Approval and Use of Labels and Labeling

Guidance 071 - Weighing and Measuring Practices In Manufacturing Operations

Guidance 072 - Material Supplier Approval Process

Guidance 073 - Storage & Distribution of Medicinal Products, Medical Devices

Guidance 074 - Control of Manufacturing and Packaging Defects Non Sterile Goods

Guidance 075 - Pest Control Procedure for GMP Facility

Guidance 076 - Raw Materials and Packaging Materials Receipt Procedure in GMP Facility

Guidance 077 - Sampling Procedure of Production Materials and Finished Goods

Guidance 078 - Water Purification, Storage and Distribution for Pharmaceutical Production

Guidance 079 - Use of a Risk-Based Approach to Establish External Quality Assurance Audit Frequency

Guidance 080 - Laboratory Reduced Testing Program

Guidance 081 - Training System for GMP Facility

Guidance 082 - Laboratory Stability Testing Procedure

Guidance 083 - Quality Risk Management Application to Identify Deviations and Events

Guidance 084 - Implementation of Real Time Release of Medicinal Bathes

GMP Standard Operating Procedures

Guidance 085 - Preventive Maintenance System for GMP Facility
Guidance 086 - Calibration System for GMP Facility
Guidance 087 - Evaluation Process Supporting Elimination of Defined Shipment Temperature Range
Guidance 088 - Determining Testing Patterns and Acceptance Criteria for Analytical Method Transfers
Guidance 089 - Quality Risk Management in Establishing Weighing Device Performance Testing Intervals
Guidance 090 - Analytical Laboratory Management
Guidance 091 - Microbiology Laboratory Management
Guidance 092 - Transfer of Analytical Methods
Guidance 093 - Quality Agreements in Pharmaceuticals
Guidance 100 - Alternatives to Formaldehyde Fogging of Clean Rooms
Guidance 101 - Clean Steam Systems for GMP Facility
Guidance 102 - Cleaning and Sterilization of Aseptic Manufacturing Equipment
Guidance 103 - Container Closure Integrity for Sterile Medicinal Products
Guidance 104 - Controlling the Microbiological Quality of Solid Oral Dosage Forms
Guidance 105 - Defining Worst Case Conditions for Aseptic Process Simulations
Guidance 106 - Explanation of Repeat Testing and Retesting During Microbiological OOS Investigations
Guidance 107 - Gamma Radiation Sterilization
Guidance 108 - Lyophilization Process
Guidance 109 - Lyophilizer Loading and Unloading Recommendations
Guidance 110 - Microbial Attributes Testing of Non-Sterile Solid Oral Dosage Forms and Materials
Guidance 111 - Microbiological Testing in Cleaning Validation for APIs and Medicinal Products
Guidance 112 - Overview of Trending of Environmental Monitoring Data for Aseptic Processing Areas
Guidance 113 - Packaging System Integrity for Sterile Medical Devices
Guidance 114 - Preventing Cross Contamination in GMP Facility
Guidance 115 - Prevention and Control of Fungal Contamination in Tablets
Guidance 116 - Sanitant Rotation in a Routine Sanitization Program
Guidance 117 - Sterilization or Depyrogenation Validation - Non Product
Guidance 118 - Unplanned Cleanroom Power Outage Time Limit and Recovery Determinations for Aseptic Processing Areas
Guidance 119 - Use of Sterilized Goggles Within the Aseptic Processing Area
Guidance 120 - Water Activity and How Does it Apply to Pharmaceutical Manufacturing

Quality and Validation Manuals

Manual - 001 Evaluation of Contaminant Options for Packing of Solid Dosage Forms
Manual - 002 Retention and Disposal of GMP Documents and Retention Samples
Manual - 003 Certificate of Materials Supplied
Manual - 004 Quality Assurance Agreements for GMP Facility
Manual - 005 Procedure for Quality Assurance Management for Contractors

GMP Standard Operating Procedures

Manual - 006 Regulatory Inspection Guideline
Manual - 007 Quality and Compliance Auditing Guideline
Manual - 008 Facility Based R&D Quality Assurance Audit
Manual - 009 Auditor Training for GMP Facility
Manual - 010 Compliance Improvements Plans for GMP Facility
Manual - 011 Archiving, Disposal and Record Management Guideline
Manual - 012 Internal Quality Assurance Agreements
Manual - 013 Audit of a Distribution Site for Medicinal Products
Manual - 014 Supplier Auditing for GMP Facility
Manual - 015 Management and Control of Master GMP Document
Manual - 016 Artwork Creation & Control of Printed Packaging Components
Manual - 017 Release of API Bulk Formulated Products & Part Finished Packs
Manual - 018 Risk Management for Computerized Systems
Manual - 019 Batch Confirmation Certification & Release by a Qualified Person
Manual - 020 Cross Contamination Risk Evaluation Process for Commercial Compounds
Manual - 021 Certificate of Analysis & Certificate of Manufacture for Medicinal Batches
Manual - 022 Pharmaceutical Product Quality Reviews
Manual - 023 Warehousing and Distribution of Commercial Products
Manual - 024 Utility Standards for GMP Facility
Manual - 025 Conducting Investigations
Manual - 026 Management and Documentation of Training for GMP Facility
Manual - 027 Definition and Documentation of Raw Data
Manual - 028 Risk Management in the Quality Assurance and Compliance Area
Manual - 029 Manufacturing Deviation Management
Manual - 30 Study Based GLP Quality Assurance Audit for Critical Phases
Manual - 31 Guideline for Development and Contents of Specifications
Manual - 33 Manufacture Packing and Shipping of Materials Ahead of Full QA Clearance
Manual - 34 Determination of Storage Periods for APIs Excipients Intermediates and Raw Materials
Manual - 35 The Preparation of Process Validation Master Plan
Manual - 36 Process Validation of Bulk Medicinal (API and Intermediate)
Manual - 37 Process Validation for Formulated Products
Manual - 38 Cleaning and Cleaning Validation of API Plant and Equipment
Manual - 39 Sterilization Process Validation
Manual - 40 Cleaning and Cleaning Validation For Formulated Products
Manual - 41 Analytical Laboratory Procedure Validation
Manual - 42 Water Quality Standard
Manual - 43 Sterility Testing Procedure
Manual - 44 Endotoxin Testing Procedure
Manual - 45 Guideline for Stability Testing for R&D

GMP Standard Operating Procedures

Manual - 46 Storage and Expiry Dating of Analytical Reagents in Laboratory

Manual - 47 Preparation & Maintenance of Stability Protocols and Stability Master Plans

Manual - 48 Commercial Stability Testing of API (Pure Bulk Medicinal)

Manual - 49 Commercial Stability Studies at Contractors

Manual - 50 R&D Laboratory Quality Assurance Record Retention Procedure

Manual - 51 Microbiological Testing for Non Sterile Medicinal Product

Manual - 52 Reference & Retention Samples

Manual - 53 Laboratory Equipment Qualification

Manual - 54 Manufacture and Microbiological Testing of Sterile API & Medicinal Product Within R&D

Manual - 55 Commercial Stability Testing For Formulated Products

Manual - 56 Environmental Monitoring

Manual - 57 Trending of Stability Data

Manual - 58 Laboratory Out of Specification Results Investigation

Manual - 59 Manufacturing Documentation

Manual - 60 Maintenance and Calibration of GMP Critical Items in Manufacturing Operations and R&D

Manual - 61 Re-treatment and Blending of API & Formulated Product

Manual - 62 In-Process Testing, Checks and Sampling

Manual - 63 Management of Returned Goods

Manual - 64 Receipt Handling and Storage of Starting & Packaging Materials

Manual - 65 Control of Packaging Operation

Manual - 66 Requirements of Facilities For Sterile and Non-sterile Medicinal Manufacturing

Manual - 67 Labeling and Packaging of Investigational Medicinal Products and APIs in R&D

Manual - 68 Principles and Responsibilities for The Management of Change in Manufacturing Operations

Manual - 69 The Validation of Facilities and Systems

Manual - 70 Information Technology Infrastructure Qualification

Manual - 71 Management of Change in Computerized System

Manual - 72 Access by Regulatory Authorities and Auditors to Electronic Records

Manual - 73 Guidelines for Generating Manufacturing Documentations

Manual - 74 Electronic Records and Electronic Signatures

Manual - 76 Out of Specifications Results Investigation Procedure

Manual - 77 Analytical Procedures and Validation

Manual - 78 Technology Transfer of Established Medicine from One Commercial Site to Other