

Process, Cleaning and Methodology Validation Procedures

In this episode you will find procedures and practical work instructions on different aspects of validation to build up an effective validation and revalidation system for your business.

In this area you will find procedures on validation-concept and procedure, revalidation procedure, method validation procedure, procedure for cleaning validation, validation of laboratory instruments, equipment specification and qualification and in-house trial procedure.

All procedures have reference of prepared Forms and Templates for effective record keeping and reporting purposes. Forms are attached at the end of each procedure. Templates are listed separately.

SOP list

VAL-005 Validation-Concept and Procedure

This procedure describes general validation concepts and practices, the way processes and systems must be qualified/validated and the confirmatory documentation required. Here you will find the philosophy of validation, responsibilities, validation approaches of design qualification, installation qualification, operational qualification, performance qualification, cleaning validation, method validation, computer validation, general and specific criteria of validation, validation documentation and change control, validation reporting, guidelines of validation acceptance criteria.

VAL-010 Revalidation Procedure

This procedure contains step by step instruction on initiation of revalidation categories, changes that warrant revalidation programs, basic steps of revalidation procedure, revalidation activities and specific responsibilities, revalidation protocols, revalidation timing, equipment checklist, revalidation discrepancy procedure, release of revalidated equipment, preparation of the revalidation reporting file.

VAL-015 Method Validation Procedure

This procedure provides a guideline for a validation Technician on the characteristics that must be considered during the validation of an analytical testing procedure. The procedures set out in this SOP apply to qualitative and quantitative analytical methods which are used to test finished goods, in-process material, excipients and raw materials in support of registration documentation and cleaning validations and management responsibilities towards completing those method validation tasks.

VAL-020 Procedure for Cleaning Validation

This SOP describes the types of cleaning process and cleaning agents of process equipments and their validation, complete instruction on cleaning validation procedure, calculation of acceptance limits for rinse and swab samples, calculation of acceptance limits for swabs, analytical method validation for cleaning, cleaning validation test protocols and change control for revalidation.

VAL-025 Validation of Laboratory Instruments

This procedure describes the validation practices for laboratory instrument/equipment to be validated or calibrated and the confirmatory documentation required showing that the instrument/equipment is capable and operating effectively for its intended purpose. This procedure has practical instruction on Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) to be performed by the qualified equipment service technician in the presence of the laboratory staff with reference to the instrument/equipment manual.

VAL-030 Equipment Specification and Qualification

This procedure describes in detail the procedures for the procurement of equipment, incorporating standardized demand specifications and Installation Qualification documentation, to ensure that equipment procured complies with in-house requirements and standards and conform to Good Engineering Practice, to detail the general procedure to be followed regarding the reporting of Factory and Site Acceptance Tests, to detail the manner by which the equipment Installation Qualification is documented.

VAL-035 In-House Trial Procedure

The purpose of this SOP is to define common procedures to follow when organizing Trials/Evaluation Studies for the purpose of process improvement, equipment capability and validation studies. It defines the responsibilities within the trial process and documents that need to be considered when preparing the Trial documentation to ensure that the trial meets GMP and where applicable validation requirements. This SOP defines the procedures for conducting in house stand-alone trials on systems, processes and equipment. There can be an overlap between a trial and validation in that Trial documentation may form part of a latter process validation, (i.e. concurrent and prospective validation) and qualifications (OQ, PQ).

Validation Guidance

Method Validation

Guidance 001 - Analytical Test Method Validation - General Guidance

Guidance 002 - Analytical Test Method Validation - Risk Assessment and Prioritization

Guidance 003 - Analytical Test Method Validation - System Suitability

Guidance 004 - Analytical Test Method Validation - Precision and Accuracy

Guidance 005 - Analytical Test Method Validation - Quantitation and Detection Limit

Guidance 006 - Analytical Test Method Validation - Linearity, Range and Specificity

Guidance 007 - Analytical Test Method Validation - Robustness

Cleaning Validation

Guidance 008 - Calculations of Residue Limits For Drug Products for Equipment Cleaning

**Guidance 009 - Guidance for Swab Sampling and Visual Inspection Locations for API
Equipment**

Guidance 010 - Product and Equipment Grouping and Worst - Case Product Selection

Guidance 011 - Rinsate and Swab Sample, Test Method Development and Validation

Guidance 012 - Visual Inspection and Quantitation

Guidance 013 - Investigating Unknown Peaks in Chromatography

**Guidance 014 - Cleaning Evaluation Documentation and Instruction - Records for
Cleaning Activities**

Other Validation

Guidance 015 - Critical Process Parameters for Drug Product

Guidance 016 - Identification of the Critical Steps for Drug Product Process

Guidance 017 - Process Validation for Drug Products and Medical Devices

Guidance 018 - Equipment Cleaning Validation for Active Pharmaceutical Ingredients

Guidance 019 - Equivalence Criteria of Impurities for API Process Validation

**Guidance 020 - Equivalency Comparison of Drug Product Validation Batch Data to
Reference Batches**

Guidance 021 - Establishing and Extending Clean Equipment Hold Times

**Guidance 022 - Evaluating Non-Cleaned Equipment Hold Times for Cleaning Validation of
APIs & Drug Products**

Guidance 023 - Evaluation of Changes for Potential Impact on Process Validation

Guidance 024 - General Guidance for Process Validation Sampling

**Guidance 025 - Guidance for Swab & Visual Inspection Sampling Locations for Drug
Products Equipment**

Guidance 026 - In-Process and Bulk Drug Product Holding Times

**Guidance 027 - Demonstration of Active Pharmaceutical Ingredient (API) Batch
Homogeneity**

Guidance 028 - Documentation Example for Continuous Quality Verification

Guidance 029 - Documentation to Support Continuous Quality Verification

**Guidance 030 - Guidance on Selection Criteria of Dose & Toxicity Data for Use in
Cleaning Limit Calculation**

**Guidance 031 - Inspection Attributes in Packaging Validation of Non-Sterile Drug
Products**

Guidance 032 - Laboratory Equipment Qualification

Guidance 033 - Matrices and Bracketing in Process Validation

**Guidance 034 - Considerations for Selecting Packaging Lot Sizes during Packaging
Validation**

Guidance 035 - Non-Sterile API Manufacturing Area Environmental Control
Guidance 036 - Packaging Validation - Potential Critical Process Parameters and Validation Practices
Guidance 037 - Process Validation Sampling for Non-Sterile Liquid, Semi Solid Drug Products
Guidance 038 - Process Validation Sampling for Non-Sterile Solid Dose Drug Products
Guidance 039 - Performance Qualification versus Process Validation
Guidance 040 - Periodic Review of Processes and Systems
Guidance 041 - Release For Sale of Drug 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

Validation Templates

Cleaning Validation-Rinsing Test Template
Cleaning Validation-Swab Test Template
Cleaning Validation-Comparative Analysis Template
Example of Installation Qualification Report
Example of Operational Qualification Report
Example of Operational Qualification Test Protocol
Example of Performance Qualification Test Protocol
Example of Validation Plan
Example of Validation Report
Example of User Requirement Specification
Example of Commissioning Plan
Example of Design Qualification Protocol
Example of Installation Qualification Equipment
Example of Installation Qualification HVAC

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Example of Installation Qualification Operating Environment

Example of Installation Qualification Pipe-work

Example of Installation Qualification Utilities

Example of Electrical Demand Specification

Example of Instrumentation Demand Specification

Example of Mechanical Demand Specification

Example of HAZOP Report

Example of Traceability Matrix Report

Example of Validation Discrepancy Form

Example of Validation Report Combined OQ_PQ

Example of Project Definition Report

Example of Project Evaluation and Closeout Report

Example of Test Protocol Change Request Form