

# Pharmaceutical Process Validation Checklist Template

 Show only Checklist

Display Style  
Default 

## Protocol Development

Review of the validation protocol, including objectives, scope, critical process parameters, acceptance criteria, and equipment/material list.

### Protocol Objective(s)

Write something...

### Batch Size (Proposed)

Enter a number...



### Validation Type (e.g., Prospective, Concurrent, Retrospective)

- Prospective
- Concurrent
- Retrospective

### Protocol Start Date (Planned)

Enter date...

### Critical Process Parameters (CPPs)

- Temperature
- Pressure
- pH
- Mixing Speed
- Humidity
- Time

### Initial Process Flow Diagram

 Upload File

## Process Understanding & Risk Assessment

Documentation of process knowledge, criticality assessment, and risk mitigation strategies.

### Detailed Process Description

Write something...

### Critical Process Parameter (CPP) - Upper Limit

Enter a number...

### Critical Process Parameter (CPP) - Lower Limit

Enter a number...

### Potential Failure Mode

- Equipment Malfunction
- Material Variation
- Operator Error
- Environmental Factors

### Risk Mitigation Strategy

Write something...

### Risk Score (Severity x Probability)

Enter a number...

### Factors Influencing Risk

- Raw Material Quality
- Equipment Calibration
- Operator Training
- Environment Control

# Equipment Qualification

Verification that critical equipment performs as intended under defined operating conditions. (IQ, OQ, PQ)

## Equipment Serial Number

## Installation Date

## Equipment Description & Specifications

## Qualification Phase (IQ, OQ, PQ)

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

## Temperature Setpoint (°C)

**Temperature Recorded (°C)**

Enter a number...

**Duration of Stability Test (hours)**

Enter time...

**Qualified By**

## Material Qualification

Confirmation of material suitability and consistency for process execution.

**Material Name**

Write something...

**Lot Number**

Enter a number...

### Receipt Date

Enter date...

### Supplier

- Supplier A
- Supplier B
- Supplier C

### Purity (%)

Enter a number...

### Supplier CoA Review Comments

Write something...

### CoA Document

 Upload File

### Material Status

- Approved
- Pending Review
- Rejected

# Process Parameter Monitoring

Tracking and documentation of critical process parameters during validation runs.

**Temperature (Run 1)**

Enter a number...

**Temperature (Run 1) - Min**

Enter a number...

**Temperature (Run 1) - Max**

Enter a number...

**Pressure (Run 1)**

Enter a number...

**Humidity (Run 1)**

Enter a number...

**Date of Reading (Run 1)**

Enter date...

### Time of Reading (Run 1)

### Reading Status (Run 1)

- Within Specification
- Out of Specification
- Unverified

## Sampling & Testing

Detailed plan for representative sampling and testing to demonstrate process capability.

### Sample Size (n)

### Sampling Method

- Random Sampling
- Stratified Sampling
- Systematic Sampling

### Sampling Date

Enter date...

### Sampling Time

Enter time...

### Test Method (e.g., USP)

USP <1>

USP <2>

In-house Method

### Result 1 (Numeric)

Enter a number...

### Result 2 (Numeric)

Enter a number...

### Test Comments/Observations

Write something...

## Data Analysis & Evaluation

Assessment of validation data against pre-defined acceptance criteria and statistical analysis.

### Batch Size

Enter a number...

### Number of Validation Batches

Enter a number...

### Acceptance Criteria Threshold (e.g., % Deviation)

Enter a number...

### Statistical Method Used (e.g., ANOVA, t-test)

- ANOVA
- t-test
- Regression Analysis
- Other

## Summary of Statistical Analysis Results

Write something...

## Process Capability (Cp/Cpk)

- Cp  $\geq$  1.33
- Cpk  $\geq$  1.33
- Other

## Justification for Acceptance/Rejection of Batch

Write something...

# Deviation Management

Documentation and investigation of any deviations occurring during the validation process.

## Deviation Description

Write something...

### Date of Deviation

Enter date...

### Time of Deviation

Enter time...

### Deviation Severity (e.g., Minor, Major, Critical)

- Minor
- Major
- Critical

### Batch Number Affected (if applicable)

Enter a number...

### Affected Area(s) (e.g., Manufacturing, QC, Packaging)

- Manufacturing
- QC
- Packaging
- Warehouse
- Other

### **Root Cause Analysis**

Write something...

### **Corrective Action Plan**

Write something...

### **Corrective Action Completion Date**

Enter date...

## **Reporting & Documentation**

Compilation of all validation activities, results, and conclusions in a comprehensive final report.

### **Executive Summary of Validation Results**

Write something...

## Complete Validation Protocol Document

 Upload File

## Number of Validation Batches Executed

Enter a number...

## Summary of Deviations and Corrective Actions

Write something...

## Report Completion Date

Enter date...

## Validation Manager Signature

## Detailed Statistical Analysis Results

Write something...

# Change Control & Continuous Improvement

Plan for managing changes to the validated process and mechanisms for continuous improvement based on validation findings.

## Date of Change Request

## Description of Change Request

## Change Category (e.g., Equipment, Process, Material)

- Equipment
- Process
- Material
- Personnel
- Other

## Estimated Impact Score (1-5, 5 being highest impact)

### Affected Areas/Departments

- Manufacturing
- Quality Assurance
- Engineering
- Validation
- Supply Chain

### Change Control Number

Write something...

### Implementation Date

Enter date...