



Pharmaceutical Cleaning Validation Checklist

Scope Definition & Planning

Defines the equipment, cleaning agents, and acceptance criteria for validation.

Objective of Cleaning Validation

Write something...

Equipment ID/Code

Enter a number...

Product(s) Processed on Equipment

- ☐ Product A
- ☐ Product B
- ☐ Other (Specify)

Brief Description of Equipment

Write something...

Date of Scope Definition

Enter date...

Justification for Cleaning Validation Approach

Write something...

Cleaning Agent Selection & Compatibility

Ensures selected cleaning agents are effective and compatible with equipment materials.

Rationale for Cleaning Agent Selection

Write something...

Cleaning Agent Type

- ☐ Alkaline
- ☐ Acidic
- ☐ Neutral
- ☐ Solvent
- ☐ Enzymatic

Cleaning Agent Name

Write something...

Cleaning Agent Concentration (%)

Write something...

pH of Cleaning Agent

Enter a number...

Material Compatibility Assessment (Equipment Materials)

Write something...

Compatibility Result

- ☐ Compatible
- ☐ Not Compatible
- ☐ Requires Further Evaluation

Cleaning Procedure Development

Details the step-by-step cleaning process, including contact times, temperatures, and rinsing steps.

Detailed Cleaning Procedure Steps

Write something...

Cleaning Agent Concentration (%)

Enter a number...

Rinse Water Temperature (°C)

Enter a number...

Rinse Time (minutes)

Enter a number...

Cleaning Agent Type

- ☐ Alkaline
- ☐ Acidic
- ☐ Neutral

Contact Time (minutes)

Water Source

- ☐ Purified Water
- ☐ Deionized Water
- ☐ Tap Water

Specific Equipment Considerations

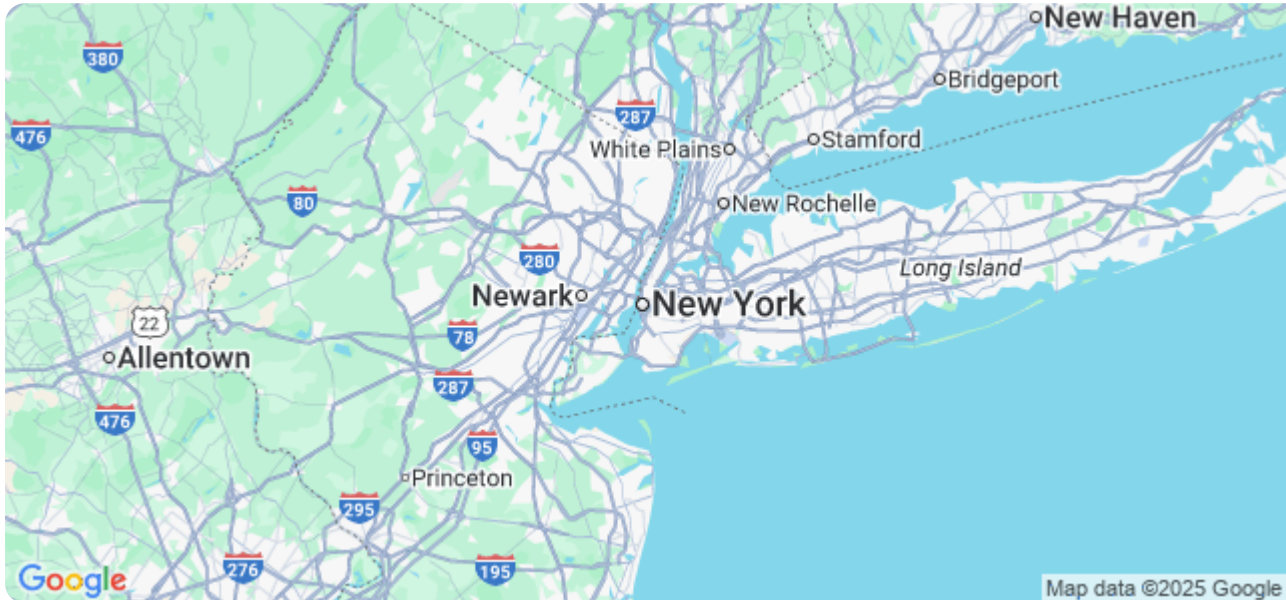
Write something...

Equipment Sampling & Monitoring

Outlines the locations and methods for sampling equipment surfaces during cleaning validation runs.

Sampling Point 1: Equipment Surface Location

 [Set My Current Location](#)



Number of Swab Samples Collected

Enter a number...

Rinse Volume (mL)

Enter a number...

Sampling Date

Enter date...

Sampling Time

Swab Material Type

- ☐ Cotton
- ☐ Nylon
- ☐ Synthetic

Sampling Location Photo (Optional)

 Upload File

Residue Limit Determination

Defines the acceptable residue limits for cleaning agents and product carryover.

Residue Limit for Cleaning Agent 1 (ppm)

Enter a number...

Residue Limit for Product Carryover (ppm)

Enter a number...

Justification for Residue Limit Selection

- ☐ Regulatory Guidance
- ☐ Industry Best Practices
- ☐ Toxicological Assessment
- ☐ Material Compatibility

Detailed Explanation of Limit Rationale

Write something...

Supporting Documentation (e.g., Toxicological Report)

 Upload File

Date Limit Established

Enter date...

Analytical Method Validation

Verifies the analytical methods used to detect and quantify residues are fit for purpose.

Method Description

Write something...

Limit of Detection (LOD)

Enter a number...

Limit of Quantitation (LOQ)

Enter a number...

Linearity (R-squared)

Enter a number...

Interference Study - Substances Tested

- ☐ Related Substances
- ☐ Excipients
- ☐ Potential Degradants
- ☐ Cleaning Agents

Accuracy - Recovery %

Validation Completion Date

Enter date...

Analyst Signature

Cleaning Validation Runs

Documents the execution of cleaning validation runs and the recorded data.

Run Date

Enter date...

Start Time

Batch Number (if applicable)

Enter a number...

Run Number

Enter a number...

Equipment State Prior to Cleaning (e.g., product residue)

Write something...

Cleaning Procedure Followed

- ☐ Procedure A
- ☐ Procedure B
- ☐ Procedure C

Deviations from Standard Procedure (if any)

Write something...

Cleaning Logs/Checklists

 Upload File

Operator Signature

Data Analysis & Evaluation

Analyzes the collected data and determines if acceptance criteria have been met.

Residue Limit for Cleaning Agent A (ppm)

Enter a number...

Residue Concentration Found (Cleaning Run 1) (ppm)

Enter a number...

Residue Concentration Found (Cleaning Run 2) (ppm)

Enter a number...

Average Residue Concentration (ppm)

Enter a number...

Acceptance Criteria Met?

- ☐ Yes
- ☐ No
- ☐ N/A

Justification for Acceptance/Rejection

Write something...

Date of Data Analysis Completion

Enter date...

Analyst Signature


Documentation & Reporting

Details the creation and review of the cleaning validation report.


Validation Protocol Summary

Write something...

Validation Protocol Document

 Upload File

Cleaning Validation Report

 Upload File

Report Completion Date

Enter date...

Report Reviewer Signature

Report Approver Signature

Deviations & Corrective Actions (if applicable)

Write something...

Change Control & Periodic Review

Describes the process for managing changes and reviewing the cleaning validation periodically.

Last Review Date

Enter date...

Summary of Review Findings

Write something...

Review Outcome

- ☐ No Changes Required
- ☐ Minor Changes Required
- ☐ Major Changes Required
- ☐ Revalidation Required

Reason for Change (if applicable)

Write something...

Revision Number

Enter a number...

Reviewer Signature

Next Review Date

Enter date...