

GMP-Compliant Cleaning Validation Analytical Methods Proformas

Form 1: Cleaning Validation Sampling Plan

Complete all fields according to GMP requirements.

Equipment Name: _____

Equipment ID: _____

Product: _____

Cleaning Procedure No.: _____

Sampling Location: _____

Sampling Method (Swab/Rinse): _____

Analyst: _____

Date: _____

Form 2: Swab Sampling Record

Complete all fields according to GMP requirements.

Swab ID: _____

Surface Area (cm²): _____

Sampling Location: _____

Solvent Used: _____

Extraction Volume: _____

Analyst: _____

Result: _____

Acceptance Criteria: _____

Form 3: Rinse Sampling Record

Complete all fields according to GMP requirements.

Equipment: _____

Final Rinse Volume: _____

Sample ID: _____

Collection Time: _____

Analytical Method: _____

Result: _____

Limit: _____

Pass/Fail: _____

Form 4: HPLC Residue Analysis Record

Complete all fields according to GMP requirements.

Method Number: _____

Column: _____

Mobile Phase: _____

LOD: _____

LOQ: _____

Sample Result: _____

% Recovery: _____

Analyst Review: _____

Form 5: TOC Analysis Record

Complete all fields according to GMP requirements.

Instrument ID: _____

Calibration Status: _____

Sample ID: _____

TOC Result: _____

Blank Result: _____

Limit: _____

Pass/Fail: _____

Form 6: Recovery Study Worksheet

Complete all fields according to GMP requirements.

Residue Applied: _____

Residue Recovered: _____

% Recovery: _____

Replicate No.: _____

Average Recovery: _____

Acceptance Criteria: _____

Form 7: Method Validation Summary

Complete all fields according to GMP requirements.

Specificity: _____

Accuracy: _____

Precision: _____

Linearity: _____

LOD: _____

LOQ: _____

Range: _____

Robustness: _____

Form 8: Cleaning Validation Final Report Approval

Complete all fields according to GMP requirements.

Protocol No.: _____

Equipment: _____

Product: _____

Conclusion: _____

QA Review: _____

QC Review: _____

Approval Date: _____