

Cleaning Validation Protocol

Company Name

Company Logo

Document No. : CVP/ Product Code-XXX/NN *

Effective Date

Revision No. :

Cleaning Validation Protocol

Name of Product:

Stage:

Product Code:

Plant:

PHARMA STATE

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1.0 Background :

Equipment X is routinely cleaned after product Y (or group of products) according to defined procedure. If group of products describe rational for choosing this grouping strategy, then describe equipment, cleaning method & cleaning agents.

2.0 Purpose :

The purpose of this study is to demonstrate that remaining product residues of previous product in a piece of equipment are always within the established acceptance criteria if the equipment is cleaned by a defined cleaning method.

3.0 Scope :

- A visual test and a chemical evaluation of the equipment shall be performed after its cleaning to demonstrate that product residue(s) (active ingredient, intermediates and / or excipients) and cleaning agent residues (exclude solvents used in process) have been removed to levels within the acceptance criteria.
- The equipment cleanliness shall be proven by testing and evaluation of samples in accordance with this protocol from N# consecutive cleans. (N#: Generally three consecutive cleans are acceptable, however, companies must determine the number adequate for their operation.)
- A report will be written assessing the data generated and thus determining the validity of the cleaning process.
- The equipment must not be used to process another product until clearance indicating that the equipment is adequately clean has been received from the validation department in accordance with procedure.

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4.0 Approval Signatures:

Following personnels are responsible for preparation, review and approval of Process Performance Qualification Protocol.

	Name/ Designation	Signature	Date
Prepared by			

	Name/ Designation	Signature	Date
Reviewed By			

	Name/ Designation	Signature	Date
Approved By			

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5.0 Responsibilities :

The responsibilities and functions are as tabulated below.

Team	Responsibility
Manufacturing Dept.	Responsible for Cleaning of Equipment
Quality Control	Responsible for performing Testing of cleaning validation samples
Quality Assurance	Responsible for review of data & approval of study
Validation Dept.	Responsible for taking Validation samples
Engineering Dept.	Responsible for review of data and approval of study

6.0 Sampling Procedure :

- Remove swab and rinse samples from the equipment as per the procedure. (Or if there is no SOP in place describe the validated sampling technique for the QA / Validation Dept. sampler).

6.1 Swab Samples:

- Swab samples should be removed according to swabbing procedure.
- The swab sampling locations are as follows:
 - **Product Residue Samples:** list of sample locations and no. of swabs to be removed.
 - **Cleaning Agent Samples:** list of sample locations and no. of swabs to be removed.
- Samples should be removed from the locations on the equipment deemed to be 'worst case' i.e. most difficult to clean locations and therefore where product is most likely to reside if cleaning has not been adequate. It is pertinent that these locations have been determined scientifically and can be rationalised if necessary.

6.2 Rinse Samples:

- Rinse samples should be removed according to procedure.
- The volume of liquid used to rinse the equipment should be detailed in Protocol. (Volume must be shown to be sufficient to cover all product contact surfaces of the equipment).
- Samples should then be sent to the QC department for analysis. Any relevant sample transfer conditions should be noted.

6.3 Microbiological Testing

- Microbiological test samples should be removed according to procedure (or if there is no SOP in place describe the sampling technique for the QA /Validation sampler).
- The microbiological testing locations are as follows:

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List of sample locations and no. of microbiological tests samples to be removed.

- Samples should then be sent to the QC department for analysis. Any relevant sample transfer conditions should be noted.

7.0 Testing Procedure :

- a. Rinse samples should be tested for:
 - Product residues in accordance with analytical protocol
 - Cleaning agent residues in accordance with analytical protocol
 - b. Swab samples should be tested for:
 - Product residues in accordance with analytical protocol
 - Cleaning agent residues in accordance with analytical protocol
 - c. Microbiological test samples should be tested for:
 - Total Aerobic Microbial Count (TAMC)
- Note the limits of quantitation and detection as well as the % recovery for the tests being performed.
 - The analytical protocol should include a calculation to convert the amount of residue detected in the sample to 100% (i.e. if the analytical validation results indicate that only 50% of spiked active / cleaning agent is recovered using the swabbing / rinse method of choice, the amount of active cleaning agent recovered per sample should be multiplied by 2 to bring result to 100%).
 - All data generated should be attached to this study and returned to the Validation department where calculations and adherence to acceptance criteria is determined.

8.0 Acceptance Criteria :

- The Visual cleanliness of the equipment must be checked and verified after cleaning according to the procedure.
- The swab / rinse sample acceptance criteria for product and cleaning agent residues as well as the microbiological test acceptance criteria should be detailed along with a rationale for the figures quoted.

9.0 Deviations :

- Please indicate whether deviations occurred during the completion of this Validation Protocol and give details especially with regard to impact on the effectiveness of the cleaning validation and with regard to corrective and preventive actions.

10.0 Revalidation:

- Define the Revalidation strategy for cleaning processes.

11.0 Abbreviations :

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12.0 Annexures :

Sr. No.	Annexure
1.	Sampling Location Diagram (For Rinse, Swab & Microbial Swab)
2.	Template for Recording Data

❖ Points To Consider:

- Surface area calculations should be performed, verified and kept on file for all equipment evaluated.
- When the worst case result recorded is less than the limit of quantitation but greater than the limit of detection for the test method, the value denoting the limit of quantitation should be used to perform the calculations.
- When the worst case result recorded is less than the limit of detection for the test being performed the value denoting the limit of detection should be used to perform the calculations. Dirty Hold Times and Clean Hold Times.
- The period and when appropriate, conditions of storage of equipment before cleaning, commonly referred to as The Dirty Hold Time (DHT) and the time between cleaning and equipment reuse, prior to additional cleaning, commonly referred to as The Clean Hold Time (CHT), should form part of the validation of cleaning procedures.
- This is to provide confidence that routine cleaning and storage of equipment does not allow potential for build up of degradation products that may not be removed by the standard cleaning procedure and does not allow potential for microbial contamination of equipment and to ensure that these potential risks are properly assessed and controlled.

* Where XXX stands for the sequential no. for Protocol
NN stands for revision no.

Where F1 stands for Format No.
AAA stands for Dept. Code
BBB stands for SOP No.
NN stands for revision no.