

Cleaning Validation Protocol Template

(Ref. SOP _____)

Project Name		Project Number	
Equipment		Serial Number	
Manufacturer		Model Number	
Process Line/Location		Protocol number	

FOR: VALIDATION OF THE CLEANING PROCEDURE FOR
[Insert Equipment name]

	WRITTEN BY:	REVIEWED BY:
Name:		
Position:		
Signature:		
Date:		

	APPROVED BY:		
Name:			
Position:			
Signature:			
Date:			

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Analyze swabs as per:

- [Enter SOP/method Number and Name]

Record all results in laboratory notebook and in appendix 5. Attach printouts of raw data to laboratory workbook or appendix 5.

- 5.2.6 Following swabbing, determine if the cleaning procedure has removed detergent residue to acceptable levels.

[Describe how you will take the rinse sample for detergent removal]

Test the control and the sample as per:

[Insert SOP reference no]

Record all results in laboratory notebook and summarize in Appendix 5

- 5.2.7 To determine the Dirty Hold Time, do not clean the equipment following manufacture for the duration specified in section 5.5. Repeat step 6.2.1 to 6.2.6. Note, Dirty Hold Time can be established during evaluation of cleaning performed on three validation runs
- 5.2.8 To determine the Clean Hold Time, do not sample the equipment following cleaning for the duration specified in section 5.5.
Store the equipment as per [SOP / normal procedure](#). Repeat step 6.2.1 to 6.2.6. Note, Clean Hold Time can be established during evaluation of cleaning performed on three validation runs

6 ACCEPTANCE CRITERIA

- 6.1.1 On inspection, all surfaces must be visually clean i.e. must be free of product and detergent residues, foaming and accumulation of water when dry.
- 6.1.2 The Maximum allowed carry-over for product residue swabs must be less than [Insert limit (not TOC limit) g/swab]
- 6.1.3 The pH and Conductivity of the rinse water samples tested for detergent must meet the BP specification for purified water.
This specification is not more than 4.3 $\mu\text{S}/\text{cm}^{-1}$ at 20°C and between 5.0 and 7.0 pH units.
- 6.1.4 All equipment must have microbial contamination at acceptable levels as follows for swabs:
- | | |
|--------------------------|--------------------------------------|
| TPC: | $\leq 1 \text{ c.f.u} / \text{cm}^2$ |
| Yeast & Mould count: | $\leq 1 \text{ c.f.u} / \text{cm}^2$ |
| <i>Pseudomonas</i> spp.: | Not Detected/ swab |
| Coliforms: | Not Detected/ swab |
| <i>E.coli</i> : | Not Detected/ swab |
| <i>Salmonella</i> spp | Not Detected/ swab |
- 6.1.5 The cleaning cycles will be considered validated on completion of three consecutive successful evaluations.
- 6.1.6 All Cleaning Procedure SOPs must be current and in place. All identified training must be completed and documented.
- 6.1.7 All analytical methods and recovery procedures must be validated. All equipment must be validated and instrumentation used for testing must be within calibration
- 6.1.8 No unexplained intervening failures may occur. When there is a deviation from one of the replicate runs, it may be removed from the sequence if the deviation is unrelated to the

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APPENDIX 1 –SAMPLING PLAN

1. Visual inspection will be performed on all accessible parts
3. Rinse sampling for detergent residue removal will be performed as follows:
3. Swab samples will be taken for product residue and microbial determination as follows:

See below for examples of rationale used

Sample No	Part	Location	Tests	Rationale
1	[insert part no]	Ref. Photo 1 attached (Arrow indicates product residue swabbing site)	Visual Inspection Product Residue Analysis Cleaning Agent Residue Analysis Microbial Determination	Difficult to clean paddle in comparison to flat surfaces in the hopper with potential of residue accumulation. Micro samples will be taken from the larger surface area around paddle. Detergent residue rinse samples will be taken from the larger surface area of the hopper
2	[insert part no]	Ref. Photo 2 attached (Arrow indicates product residue swabbing site)	Visual Inspection Product Residue Analysis Microbial Determination	Cleaning the feed screw is difficult in comparison to flat surfaces with potential of residue accumulation. Micro samples will be taken covering the surface area of the feed screw. Detergent residue rinse samples will not be taken from the feed screw due to the design of the equipment.
3	[insert part no]	Ref. Photo 3 attached (Arrow indicates product residue swabbing site)	Visual Inspection Product Residue Analysis Microbial Determination	Difficult to clean due to grooves present on the compactor rolls with potential of residue build up. Micro samples will be taken covering the surface area of the compactor rolls. Detergent residue rinse samples will not be taken due to the design of the compactor rolls.

[Refer to photos of swab locations]

All Acceptance Criteria Met Yes/ No _____	Initial /Date
Record all discrepancies/ further actions in Appendix 8	
Reviewed By	Date: