



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning and Sterilization of Filling Assembly

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 8	

1.0 OBJECTIVE:

To lay down a procedure for cleaning and sterilization of machine parts and filling assembly.

2.0 SCOPE:

This SOP is applicable for Cleaning and Sterilization of Filling & Sealing Assembly.

3.0 RESPONSIBILITY:

Operating Person: Production

4.0 ACCOUNTABILITY:

Head-Production

5.0 ABBREVIATIONS:

%	Percent
μ	Micron
IPA	Isopropyl Alcohol
Ltd	Limited
Ltr	Liters
LAF	Laminar Air Flow
LPG	Liquefied Petroleum Gas
Mfg.	Manufacturing
No.	Number
pH	Potential of Hydrogen
Pvt	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless Steel
WFI	Water for Injection
SLS	Sodium Lauryl Sulphate

6.0 PROCEDURE:

6.1 Cleaning of Filling Assembly and Machine Parts:

- 6.1.1 Switch off the electric supply of the machine after completion of filling operation.
- 6.1.2 The Filling Assembly subjected to Cleaning shall bear a “**To Be Cleaned**” Status Label.
- 6.1.3 Dismantle the machine parts send to equipment wash area for cleaning. (Machine parts are listed in Annexure no. II, III and IV as per respective section)
- 6.1.4 Collect sufficient quantity of Purified Water in a SS container and dip the filling assembly for 15-20 minutes and then clean external surface with clean moping pad.
- 6.1.5 Apply 0.2 % non-ionic liquid solution of Sodium Lauryl Sulphate on all parts and clean it by using nylon scrubber (if required).



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- 6.1.6** Clean all the machine parts thoroughly with Purified water for 40-50 minutes.
- 6.1.7** Clean all the machine parts thoroughly with water for injection for 40-50 minutes.
- 6.1.8** Rinse by apply a jet of WFI and drain approx. 50 Ltr. WFI through machine parts and other filling assembly.
- 6.1.9** Intimate QA person and collect all the machine parts in a container filled with WFI approx 20 Ltr. and dip for 10 minutes. After that collect 100 ml of WFI from container and send to IPQA/QC for trace analysis for SLS / as per WFI Quality Parameters, i.e. pH, Conductivity. Rinse water sample is applicable for product contact parts i.e. the parts that came in direct contact with the product.
- 6.1.10** Dry the machine parts and filling assembly by applying 0.2 μ Filtered compressed air and after drying keep it Under LAF.
- 6.1.11** Wipe all the guards, machine body & conveyor belt with WFI using lint free cloth.
- 6.1.12** Clean all the guards, machinery & conveyor belt using 70% IPA solution spraying all over the Machine and by lint free cloth.
- 6.1.13** Sanitize the surrounding area of the machine using disinfectant solution or 70 % IPA solution (Where applicable).
- 6.1.14** After QA clearance, all machine parts and tubing to be sterilized in Autoclave as per validated load pattern.
- 6.1.15** Affix status label on the Filling Assembly” **READY FOR STERILIZATION**”.
- 6.1.16** Sterilize the Filling Assembly in Steam Sterilizer as per respective SOP.
- 6.1.17** Record the cleaning activity as per checklist mentioned in the **Annexure-I**.
- 6.1.18** Refer SOP no. HPD/015 for cleaning of machine parts used in DPI section.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning Check List for Filling Assembly	
Annexure-II	Cleaning And Rinse Water Sampling Details Of Machine Parts Used	
Annexure-III	Cleaning And Rinse Water Sampling Details Of Machine Parts Used	
Annexure-IV	Pictorial Display Of Cleaning Procedure For Machine Parts	

ENCLOSURES: SOP Training Record



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8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – I CLEANING CHECK LIST FOR FILLING ASSEMBLY

Previous Product : _____ **Date :** _____

Product Name : _____ **Batch No :** _____

S.No.	CLEANING STEPS	STATUS*
1.	Dismantle the Filling Assembly and machine parts.	
2.	Remove the Gasket, Opening Parts and silicon tubing.	
3.	Dip the Filling Assembly and accessories in a SS container containing Purified Water for 15-20 minutes.	
4.	Clean the filling assembly and machine parts with 0.2 % SLS solution.	
5.	Clean the filling assembly and machine parts with purified water for 40-50 minutes.	
6.	Clean the filling assembly and machine parts with WFI for 40-50 minutes.	
7.	Rinse the filling assembly and machine parts with Water For Injection.	
8.	Inform the QA Person to collect the Swab / Rinse Water Sample.	
9.	Dry the Filling Assembly and Accessories with 0.2 μ Filtered Compressed Air.	
10.	Affix the 'Status Label' on the Vessel.	
11.	Perform the Sterilization of the Cleaned Filling Assembly and Accessories in Steam Sterilizer.	

* Put '√' mark if activity performed, OR Put 'X' if the activity not performed.

Done By:
(Production Operator)
Sign & Date:

Checked By:
(Officer / Executive – Production)
Sign & Date:

Verified By:
(Officer / Executive - QA)
Sign & Date:



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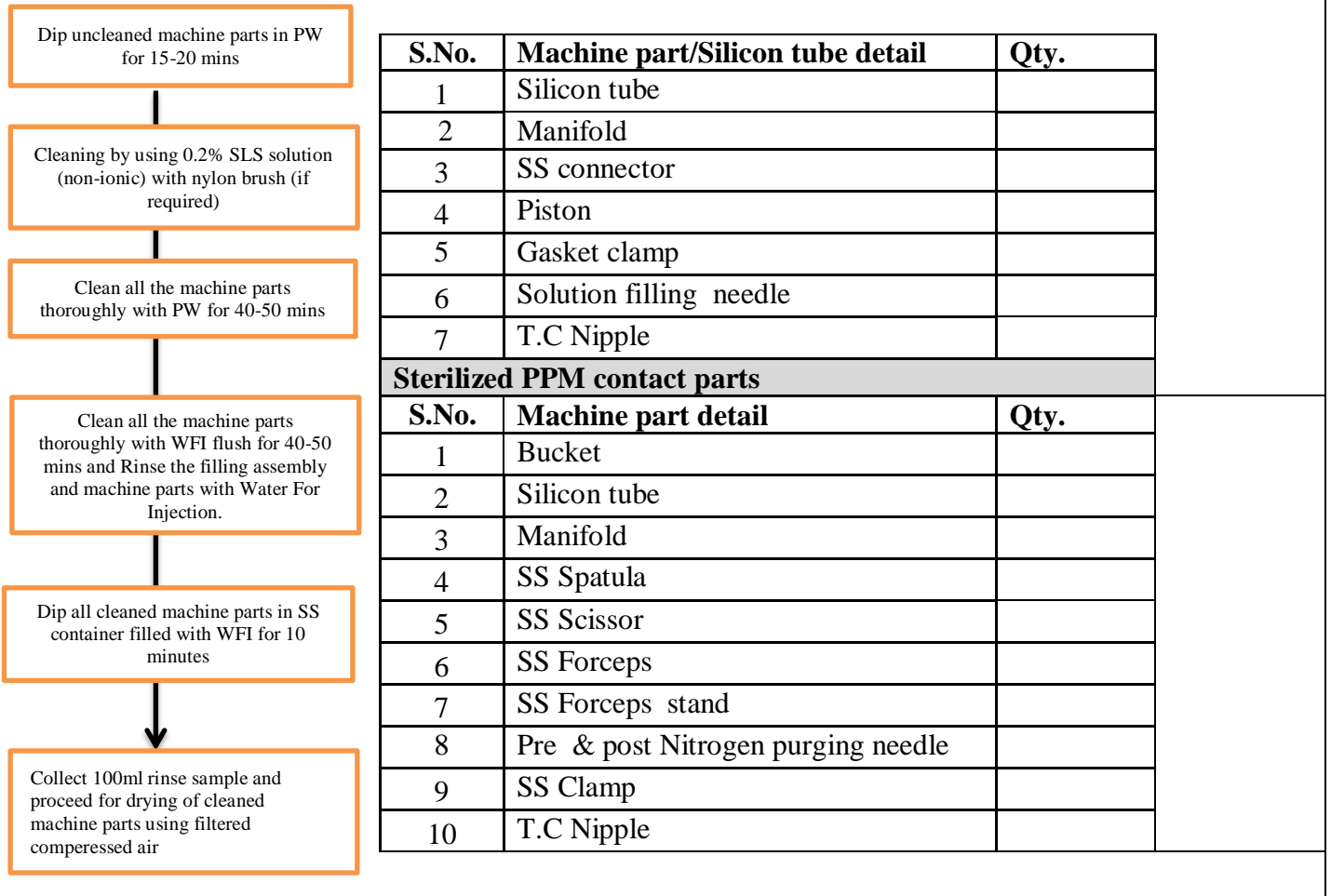
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ANNEXURE- II

CLEANING AND RINSE WATER SAMPLING DETAILS OF MACHINE PARTS USED IN AMPOULE SECTION (I BLOCK)





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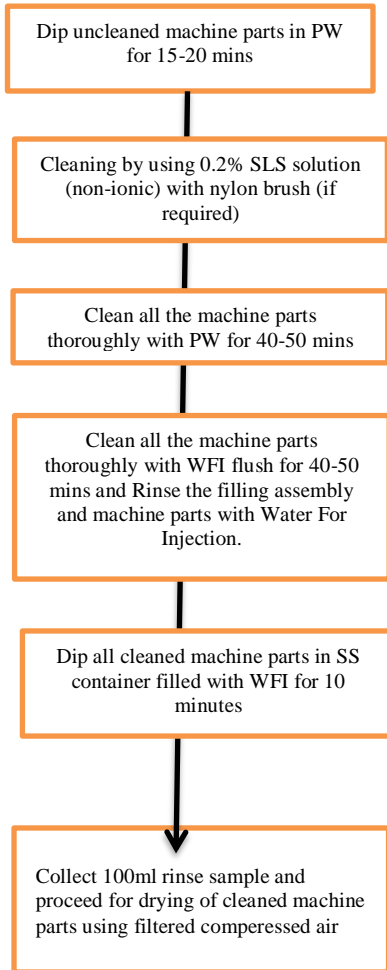
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ANNEXURE- III

CLEANING AND RINSE WATER SAMPLING DETAILS OF MACHINE PARTS USED



Product Solution contact Parts		
S.No.	Machine part/Silicon tube detail	Qty.
1	Silicon tube	
2	Manifold	
3	SS connector	
4	Solution Filling needle	
5	Nitrogen purging needle	
6	Capping head assembly	
7	Dropper head assembly	
8	Nut of Hopper	
Sterilized PPM contact parts		
S.No.	Machine part detail	Qty.
1	Orientator (Vial hopper)	
2	Dropper hopper	
3	Screw cap hopper	
4	Vial chute	
5	Dropper chute	
6	Screw cap chute	
7	SS Scissor	
8	SS Forceps	
9	SS Forcep stand	



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ANNEXURE- IV

PICTORIAL DISPLAY OF CLEANING PROCEDURE SEQUENCE FOR MACHINE PARTS



1. DIP UNCLEANED MACHINE PARTS IN PW FOR 15-20 MINS

2. CLEANING BY USING 0.2% SLS SOLUTION (NON-IONIC) WITH NYLON BRUSH (IF REQUIRED)



3. CLEAN ALL THE MACHINE PARTS THOROUGHLY WITH PW FOR 40-50 MIN

4. CLEAN ALL THE MACHINE PARTS THOROUGHLY WITH WFI FLUSH FOR 40-50 MINS



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5. DIP ALL CLEANED MACHINE PARTS IN SS CONTAINER FILLED WITH WFI FOR 10 MINUTES

6. COLLECT APPROX 100ML RINSE SAMPLE (BY TILTING THE CONTAINER) AND PROCEED FOR DRYING OF CLEANED MACHINE PARTS USING FILTERED COMPRESSED AIR