



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Sterilization of Machine Parts and Accessories	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Sterilization of Machine parts & Accessories.

2.0 SCOPE:

This SOP is applicable for Cleaning and Sterilization of Machine parts & Accessories at

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 CLEANING OF FILLING ASSEMBLY:

- 6.1.1** The Filling Assembly subjected to Cleaning shall bear a **“To Be Cleaned”** Status Label.
- 6.1.2** Dismantle the Filling Assembly and transfer to the Pre Wash room through the Dynamic pass box.
- 6.1.3** Use the sufficient quantity of Purified Water for the cleaning of filling assembly for 10 minutes and then clean external surface with clean moping pad.
- 6.1.4** Use the sufficient quantity of WFI for the cleaning of filling assembly for 10 minutes and then clean external surface with clean moping pad.
- 6.1.5** Apply a jet of WFI & drain 50 Ltr. WFI through filling nozzle & other filling assembly.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Sterilization of Machine Parts and Accessories	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.1.6 Dry the Filling Assembly by applying 0.2 μ Filtered Compressed Air and after drying wrap it with parchment paper.
- 6.1.7 Affix a status label on the Filling Assembly **“READY FOR STERILIZATION”**.
- 6.1.8 Sterilize the Filling Assembly in HPHV Steam Sterilizer as per respective SOP.
- 6.1.9 Cleaning shall be performed as per Checklist format Shown in **Annexure-I**.

6.2 CLEANING OF PRESSURE VESSEL:

- 6.2.1 The Pressure Vessel subjected to Cleaning shall bear a **“To Be Cleaned”** Status Label.
- 6.2.2 Dismantle the Pressure Vessel by opening the Lid from the Top.
- 6.2.3 Remove the Gasket, Opening Parts and SS Pipe.
- 6.2.4 Bring the Pressure Vessel in upright position and empty it, if any content is there.
- 6.2.5 Keep the Pressure Vessel in upright Position and apply a jet of Purified Water from the Bottom.
- 6.2.6 Keep the Pressure Vessel in upright Position and apply a jet of Water for Injection from the Bottom.
- 6.2.7 Use the sufficient quantity of Purified Water for the cleaning of Gasket, Opening Parts and SS Pipe for 10 minutes and then clean with moping pad.
- 6.2.8 Use the sufficient quantity of WFI for the cleaning of Gasket, Opening Parts and SS Pipe for 10 minutes and then clean with moping pad.
- 6.2.9 Dry the Gasket, Opening Parts and SS Pipe by applying Compressed Air.
- 6.2.10 Assemble the Gasket, Opening Parts and SS Pipe and Lid on the Pressure Vessel.
- 6.2.11 Sanitize the pressure vessel with pure steam followed by dry the pressure vessel with 0.2 μ filtered compressed air.
- 6.2.12 If required perform the Sterilization of the Cleaned Pressure Vessel in HPHV Steam Sterilizer.
- 6.2.13 Cleaning shall be performed as per Checklist format Shown in **Annexure-II**.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Sterilization of Machine Parts and Accessories	Effective Date:
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Issue Date:	Page No.:

7.0 ABBREVIATION:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
Mfg.	Manufacturing
QA	Quality Assurance
UV	Ultraviolet Light

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning Check List For Machine Parts	
Annexure -II	Cleaning Check List For Accessories	

9.0 DISTRIBUTION:

- Controlled Copy No.1 Production Department
- Master Copy Quality Assurance

10.0 REFERENCE:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



PHARMA DEVILS

PRODUCTION DEPARTMENT

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Issue Date:	Page No.:

ANNEXURE – I

	CLEANING CHECK LIST FOR MACHINE PARTS

Previous Product: _____ **Date** : _____

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

S.No.	CLEANING STEPS	STATUS*
1.	Dismantle the Filling Assembly.	
2.	Remove the Gasket, Opening Parts, and the Silicon tubing.	
3.	Clean the Filling Assembly and accessories by Purified Water for 10 minutes.	
4.	Clean the Filling Assembly and accessories by Water For Injection for 10 minutes.	
5.	Rinse the Filling nozzle and filling assembly with 50 L Jet of Water For Injection (Thrice).	
6.	Inform the QA Person to collect the Swab/Rinse Water Sample.	
7.	Dry the Filling Assembly and Accessories with 0.2 μ Filtered Compressed Air.	
8.	Affix the 'Status Label' on the Vessel.	
9.	Perform the Sterilization of the Cleaned Filling Assembly and Accessories in HPHV 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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Issue Date:	Page No.:

ANNEXURE – II

	CLEANING CHECK LIST FOR ACCESSORIES

Previous Product: _____ **Date** : _____

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

S. No.	CLEANING STEPS	STATUS*
1.	Dismantle the Pressure Vessel by opening the Lid from the Top.	
2.	Remove the Gasket, Opening Parts, and the SS Pipe.	
3.	Invert the Vessel and remove the contents if any.	
4.	Keep the Vessel in an upright position and apply a jet of Purified Water from the bottom.	
5.	Wash the Vessel, Gasket, Opening Parts and the SS Pipe with Purified Water by applying a jet with flexible Hosepipe. Repeat this process thrice.	
6.	Rinse the Vessel, Gasket, Opening Parts and the SS Pipe with Water For Injection by applying a jet with flexible Hosepipe.	
7.	Inform the IPQA Chemist to collect the Swab / Rinse Water Sample.	
8.	Assemble the Gasket, Opening Parts, SS Pipe and lid after draining out all the water.	
9.	Affix the 'Status Label' on the Vessel.	
10.	Perform the Sterilization of the Cleaned Pressure Vessel in HPHV Steam	

* 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: