



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning of Compounding & Holding Vessel Along with Product Line, Filter Housing & Pump by Manual Method

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 3	

1.0 OBJECTIVE:

To lay down a procedure for Cleaning of Compounding & Holding Vessel along with Product Line, Filter Housing & Pump by Manual Method.

2.0 SCOPE:

This SOP is applicable for Cleaning of Compounding Vessel, Holding Vessel, Cartridge Filter Housing and SS Product Pipe Lines by manual method.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

Ltd.	Limited
SOP	Standard Operating procedure
QA	Quality Assurance
No.	Number
CIP	Clean In Place
ID No.	Identification Number
WFI	Water for Injection
PLC	Programmable Logic Control
PVT	Private

6.0 PROCEDURE:

6.1 CHECKS & PRECAUTIONS:

6.1.1 Check and ensure the availability of Electricity.

6.1.2 Visually inspect for the emptiness of Compounding & Holding Vessel before start of CIP.

6.2 CLEANING OF COMPOUNDG VESSEL WITH PUMP, FILTER HOUSING & PIPELINES:

6.2.1 Connect the flexible hose to the WFI loop& second end with spray ball, Open the bottom outlet of tank by keeping Vent valve open.

6.2.2 Start the flushing for 4-5 minutes through spray ball & wait for complete Flushing water come out from tank.

6.2.3 Close the Compounding vessel bottom valve & collect approximately 500 L WFI and operate the stirrer at speed of 100- 150 RPM, then start the pump for minimum 4 minutes for efficient cleaning of circulation line & pump



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning of Compounding & Holding Vessel Along with Product Line, Filter Housing & Pump by Manual Method

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	2 of 3	

- 6.2.4 Open the bottom valve of the vessel and pass the water through series of filter 1.2 micron, 0.6 micron and final filter 0.2 micron along with product line, up to room drain.
- 6.2.5 Visually inspect the vessel by opening the main hole of vessel. Remove stains/left over if any using spraying WFI for at least 3 minutes. (150 L of WFI).
- 6.2.6 Repeat the step No. 6.2.3 once again.
- 6.2.7 Open the bottom valve of vessel & collect wash water sample from drain tube in clean container (in case of product change over only) & drain the remaining water from vessel.
- 6.2.8 Collect the wash water sample and send the sample to QA for residual analysis with due identification & intimation slip.
- 6.2.9 Close all the open ends with SS blind / bacterial barrier paper.
- 6.2.10 Clean the external surface of vessel, gaskets and product feeding ports with lint free mop dipped with WFI/IPA 70% v/v) & dry the surfaces.
- 6.2.11 Record the equipment cleaning details in respective Equipment log as per the SOP. Affix the status label as per SOP. Proceed further after clearance from QA.
- 6.2.12 In case of failure of wash water analysis Repeat the step 6.2.3 to 6.2.7

6.3 CLEANING OF HOLDING VESSEL WITH FILTER HOUSING, PUMP AND PIPELINES-

- 6.3.1 Disconnect the discharge cross assembly from product transfer line and connect the product line after final filter with drain to room drain.
- 6.3.2 Connect the flexible hose to the WFI loop & wash all the opening, manhole and sampling port at middle portion of tank with WFI. Remove the gasket from its groove and wash with WFI.
- 6.3.3 Collect approximately 500 L WFI and operate the stirrer at speed of 100- 150 RPM, then start the pump for minimum 4 minutes for efficient cleaning of circulation line & pump.
- 6.3.4 Uniform spraying of WFI shall be checked from view glass and visually verify that water spray reaches to all surfaces of vessel and also the main hole of vessel .Open the discharge vale after pump and pass the water along with product line up to room drain.
- 6.3.5 Visually inspect the vessel by opening the main hole of vessel. Remove stains/left over if any using spraying WFI for at least 3 minutes. (150 L of WFI).
- 6.3.6 Open the bottom valve of vessel & collect wash water sample from drain tube in clean container (in case of product change over only) & drain the remaining water from vessel.
- 6.3.7 Collect the wash water sample and send the sample to QA for residual analysis with due identification & intimation slip.
- 6.3.8 Close all the open ends with SS blind / bacterial barrier paper.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning of Compounding & Holding Vessel Along with Product Line, Filter Housing & Pump by Manual Method

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	3 of 3	

6.3.9 Clean the external surface of vessel, gaskets and product feeding ports with lint free mop dipped with WFI/IPA 70% (v/v) & dry the surfaces.

6.3.10 Record the equipment cleaning details in respective Equipment log as per the SOP. Affix the status label as per SOP. Proceed further after clearance from QA.

6.3.11 If wash water report is negative then repeat the step **6.3.3** to **6.3.8** until sample had been passed.

6.3.12 Relocate the gasket & manhole lid on their place & secure the lid by locking nuts if required.

7.0 ANNEXURES:

Not Applicable

8.0 DISTRIBUTION:

- Controlled Copy No.1 Quality Assurance
- Controlled Copy No.2 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