



**Title:** Sterilization of WFI Storage Tank, Loop line and Vent Filter

<b>SOP No.:</b>		<b>Revision No.:</b>	00
<b>Effective Date:</b>		<b>Supersedes No.</b>	Nil
<b>Review Date:</b>		<b>Page No.</b>	1 of 4

**1.0 OBJECTIVE:**

To lay down a procedure for Sterilization of WFI Water Storage Tank, Loop line & Vent Filter.

**2.0 SCOPE:**

This SOP is applicable for Sterilization of WFI Water Storage Tank, Loop line & Vent Filter at .....

**3.0 RESPONSIBILITY:**

Officer/Executive - Engineering

**4.0 ACCOUNTABILITY:**

Head – Engineering

**5.0 DEFINITION:**

NA

**6.0 PROCEDURE:**

**6.1 STERILIZATION OF WFI STORAGE TANK & VENT FILTER**

- 6.1.1 Drain all the Water for Injection (WFI) from the storage tank through Diaphragm valve.
- 6.1.2 Close the Diaphragm valves which allows steam flow towards Loop Line.
- 6.1.3 Open the pure steam (Pneumatic) valve to allow the steam into the WFI storage tank.
- 6.1.4 Back Pressure Release Valve (BPRV) prevents back flow of steam from WFI Storage tank.
- 6.1.5 Hold the pure steam in WFI storage tank for 30 minutes when the temperature is achieved at 121°C and pressure 1.5 kg/cm<sup>2</sup>.
- 6.1.6 Vent filter is also sterilized at the same parameters which is installed in WFI Storage tank.
- 6.1.7 Record the details of sterilization of WFI storage tank & Vent Filter in Annexure-I.
- 6.1.8 After integrity of vent filter sterilization of WFI storage tank shall be performed and activity shall be recorded in Annexure-I.

**Frequency of Sterilization of WFI Storage tank & Vent Filter:** Monthly ± 5 Days.



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## 6.2 STERILIZATION OF WFI LOOP LINE

- 6.2.1 Close the Diaphragm valves which allows steam flow towards WFI Storage Tank.
- 6.2.2 Open the pure steam valve (Pneumatic) to allow the steam into the Loop Line.
- 6.2.3 Hold the pure steam in Loop Line for 30 minutes when the temperature is achieved at 121°C and pressure 1.5 kg/cm<sup>2</sup>.
- 6.2.4 Record the details of sterilization of Loop Line in Annexure-II.

**Frequency of Sterilization of WFI Loop Line:** Monthly ± 5 Days

## 7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
Pvt.	Private
Ltd.	Limited
NA	Not Applicable
WFI	Water for Injection

## 8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sterilization Record of WFI Storage Tank and Vent Filter	
Annexure-II	Sterilization Record of WFI Loop Line	

## 9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Head Engineering

## 10.0 REFERENCES:

In House

## 11.0 REVISION HISTORY:

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



