



Title: Sanitization of WFI Storage and Distribution System

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1.0 OBJECTIVE:

To lay down a procedure for Sanitization of WFI Storage & Distribution System.

2.0 SCOPE:

This SOP is applicable for Sanitization of WFI Storage & Distribution System.

3.0 RESPONSIBILITY:

Operator / Operating Person- Engineering

4.0 ACCOUNTABILITY

Head Engineering

5.0 ABBREVIATIONS:

14.28PSI 1Kg/cm²
°C Degree Centigrade
ID Identification No.
NLT Not Less Than
QC Quality Control
PSG Pure Steam Generator

6.0 PROCEDURE:

6.1 Before carrying out sanitization activity intimate to user department as per Annexure-III “**Intimation for Sanitization**”.

6.2 Before carrying out sanitization activity drain the WFI water from storage tank through bottom valve & distribution loop by opening respective valve.

6.3 Remove the vent filter from its housing before sanitization activity to check the condition of filter visually for any damage and shall be removed for integrity testing after three month of usage.

6.4 Replace the existing mounted vent filter with New or Integrity test approved vent filter and mount it in filter housing properly.

6.5 Used vent filter shall be send for integrity testing and shall be used again on next sanitization, if it passes the Integrity test as per SOP.

6.6 Record the details of vent filter replacement as per **Annexure – I** of SOP.

6.7 During sanitization check and ensure that online print interval time is 10 minutes for data recording.

6.8 Replacement Procedure of Centrifugal Pump:

6.8.1 Close the respective diaphragm valve from storage tank outlet whose pump is to be replaced.



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- 6.8.2** Remove the gasket from both sides i.e ; at the outlet of storage tank and other one from the inlet of centrifugal pump. Check the TC gasket for any damage, if require then replace the gasket with the new one & note down the same under remark column.
- 6.8.3** After removal of inlet pipeline from the first pump reconnect it with standby Centrifugal pump.
- 6.8.4** Check and ensure that the gasket are properly fitted and TC clamp is properly tightened.
- 6.8.5** Standby pump shall be changed before sanitization and same will remain in service till next sanitization.
- 6.8.6** Fill the details in respective prescribed **Annexure-V** titled as “**Replacement Log of Centrifugal Standby Pump**”.

6.9 Procedure for Sanitization of Distribution Line:

- 6.9.1** Stop the TOC analyzer system and close the respective sampling valve before carrying out sanitization activity.
- 6.9.2** Open the inlet PSG steam valve and close the storage tank outlet valve and maintain the flow of pure steam inside the distribution line.
- 6.9.3** Flow of steam will raise the temperature of distribution loop line, note down the temperature of the loop, it should not be less than 121°C.
- 6.9.4** After achieving temperature of NLT 121°C in return line, sanitization cycle will hold for one hour and record the details in **Annexure – II**.
- 6.9.5** During holding of one hour, record the temperature of distribution line with a frequency of 10 minutes in **Annexure -II**.
- 6.9.6** After holding of one hour drain out the steam condensate by opening respective user point’s valve of distribution line and from respective valve of storage tank.
- 6.9.7** Record the log of sanitization as per **Annexure – II**.

6.10 Procedure for Sanitization of WFI Storage Tank:

- 6.11** Drain the accumulated water of steam condensate from WFI storage tank through respective valve.
- 6.12** Check and ensure that WFI water distribution valve of storage tank should be in closed condition and open the steam feeding valve to feed pure steam in WFI water storage tank.
- 6.13** Flow of pure steam will raise the temperature of WFI storage tank up to NLT 121°C.
- 6.14** After achieving temperature of NLT 121 °C in WFI storage tank hold the same for one hour & record the temperature reading of WFI and vent filter with a time interval of 10 minutes ± 02 minutes as per **Annexure – II**.



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- 6.15 In case the temperature of loop goes below 121°C during sanitization holding cycle then re-perform the sanitization activity again.
- 6.16 After completion of one hour sanitization holding activity drain the steam condensate water from storage tank by opening drain valve & tank to pump outlet line water shall be drained by opening respective valve.
- 6.17 Record the sanitization details as per **Annexure –II. “WFI System Sanitization Record”**.
- 6.18 After completion of sanitization activity put the system in operation mode and starts the TOC analyzer by opening respective valve.
- 6.19 Drain the WFI water from storage tank through bottom valve for starting five minute and after draining check and ensure that all the WFI distribution parameter are well within defined limit.
- 6.20 Engineering shall intimate QC department to collect the sample for the analysis of pH & conductivity as per **Annexure- IV “Request for sample collection”**.
- 6.21 As per QC analysis report, WFI shall be release after intimation **Annexure- III “Intimation of Sanitization”**.
- 6.22 After completion of sanitization activity, operator shall update the status board, sanitization schedule & check the relevant document of sanitization activity for completeness.
- 6.23 Frequency of the sanitization shall be one month \pm 7 days or whenever required. Sanitization activity shall be performed as per schedule date defined in **Annexure – I**.
- 6.24 **Set parameter details of HMI:**





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7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	WFI System Sanitization Schedule	
Annexure-II	WFI System Sanitization Record	
Annexure-III	Intimation of Sanitization	
Annexure-IV	Request for sample collection	
Annexure-V	Replacement Log Of Centrifugal Standby Pump	

ENCLOSURES: SOP training record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Not applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



PHARMA DEVILS

ENGINEERING DEPARTMENT

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ANNEXURE – I WFI SYSTEM SANITIZATION SCHEDULE

Equipment ID:
Year:

Location:
Capacity:

S.No.	Month	Sanitization Plan Date	Sanitization Actual date	Done By Sign & Date	Reviewed By Sign & Date	Remark

Note: - Frequency of sanitization is One month ± 7 Days

Prepared By (Engg.)
Sign & Date

Checked By (Engg.)
Sign & Date

Approved By (QA)
Sign & Date



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ANNEXURE – II
WFI SYSTEM SANITIZATION RECORD

Area/ Block:	Loop No.:
Tank ID:	Pump ID:
Sanitization Done Date:	Sanitization Next Scheduled Date:
Activity Start Time:	
Activity Stop Time:	

S.No	Description	Time	Temp.	Observation
I	Sanitization of WFI Distribution System			
1	Sanitization start time & return loop temperature after achieving temperature (NLT 121° C) in return loop	Time		
		Temp.		
2	Vent filter temperature reading with time interval of 10 ± 02minutes during holding time	Time		
		Temp.		
3	Supply Line Pressure during holding time			
4	Return loop temperature (NLT 121 ° C) reading with time interval of 10 ± 02minutes of start time	Time		
		Temp.		
5	Sanitization End time (After 1 hour circulation)			
II	Sanitization of WFI Storage tank			
1	Sanitization start time & tank temperature after achieving temperature (NLT 121° C) in tank	Time		
		Temp.		
2	Vent filter temperature reading with time interval of 10 ± 02minutes.	Time		
		Temp.		
3	Tank inlet pure steam pressure during holding time			
4	WFI temperature (NLT 121 ° C) reading with time interval of 10 ± 02minutes after start time.	Time		
		Temp.		
5	Sanitization End time (After 1 hour circulation)			

Remark:-

Done By (Engg.)
(Sign & Date)

Review By (Engg.)
(Sign & Date)

Verified By (QA)
(Sign & Date)



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ANNEXURE – III
INTIMATION OF SANITIZATION

From: Engineering Department

Date:

Sanitization Schedule Date:

Sanitization Execution Date & Time:

Intimate by (Engg.):
Sign & date

Intimation before Sanitization

To:

Block	Department	Name	Date	Time	Sign

Sanitization Completion Date & Time:

Intimation after Sanitization (As per QC analysis report)

Block	Department	Name	Date	Time	Sign

Prepared By (Engg.):
Sign & Date

Review By (Engg.)
Sign & Date

Remark:-Water can be released as per sample status received from QC for production purpose.



PHARMA DEVILS
ENGINEERING DEPARTMENT

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ANNEXURE – IV
REQUEST FOR SAMPLE COLLECTION

From: Engineering Department

Name of the Sample:

Sampling point ID:

Intimation By:

Time:

Date & Sing:

Date:

To: Quality Control Department

S.No.	Test Required	Standard limit (as per SOP)	Actual Limit	Result Status (Passes/Fails)	Remarks

Sample Received By
(QC Dept.):
Sign & Date

Sample Analyzed By
(QC Dept.):
Sign & Date

Report Verified By
(QA Dept.):
Sign & Date

Remark:-Water can be released as per sample status received from QC for production purpose.

