



Title: Sanitization of Purified Water Storage and Distribution System

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1.0 OBJECTIVE:

To lay down a procedure for Sanitization of Purified Water Storage & Distribution System

2.0 SCOPE:

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

3.0 RESPONSIBILITY:

Officer / Executive Engineering

4.0 ACCOUNTABILITY

Head – Engineering

5.0 ABBREVIATIONS:

°C	Degree Centigrade
ID	Identification No
NLT	Not Less Than
QA	Quality Assurance
QC	Quality Control
ER	Engineering
LL	Low Low
L	Low
H	High
HH	High High

6.0 PROCEDURE:

6.1 Officer / Executive Engineering shall prepare a sanitization schedule as per **Annexure- I “Purified Water System Sanitization Schedule”**.

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

6.3 Remove the vent filter from its housing before sanitization and check the condition visually.

6.4 Then replace the New/Integrity test approved vent filter with old one and mount it in filter housing properly. Handling & integrity test activity of vent filter is carried out as per SOP.

6.5 Used vent filter will send for integrity testing and will be used again on next sanitization if it passes Integrity test.

6.6 Alternate Pump (1 or 2) shall be used for sanitization. Standby pump shall be changed before sanitization (Refer point no. 6.7) and it will be continue for next sanitization time.

6.7 Replacement procedure of centrifugal pump are as mentioned below:

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



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- 6.7.2** Remove the gasket from both sides ie; at the outlet of storage tank and other one at inlet of centrifugal pump. If gasket found damage then replace the gasket by new one and same shall be written under remark column.
- 6.7.3** After removal of inlet pipeline from the first pump reconnect it with standby Centrifugal pump.
- 6.7.4** During reconnecting of pipeline check the gasket for properly inserted and tight the TC clamp.
- 6.7.5** Open the diaphragm valve of Storage tank & run the centrifugal pump and ensure that there is no leakage.
- 6.7.6** Fill the details in respective prescribed **Annexure-V** titled as “**Replacement Log of Centrifugal Standby Pump**”.

Note: After replacement of pump sanitization of system is compulsory.

- 6.8** Collect the Purified Water approximately 1600 ltr. for 3KL & 3000 ltr. for 5 KL during sanitization of Purified water storage tank & Distribution Loop.
- 6.9** Open boiler Inlet Steam line valve in storage tank jacket.
- 6.10** Heater inside the Vent Filter Housing turns on automatically at the time of Sanitization.
- 6.11** Flow of steam will raise the temperature of Purified water, inside the Tank and wait till the water temperature rises. Purified water tank temperature should be NLT 80°C.
- 6.12** When return loop temperature is above than 80°C then circulate this hot water in distribution loop line for 1 hour.
- 6.13** Drain out the hot water inside the tank by opening its bottom valve and from user points.
- 6.14** When water level in purified water tank is below its LL level sensor then distribution pump will stop automatically and the balanced quantity of hot purified water is to be drained off from the tank by drain valve.
- 6.15** After draining of hot water, collect fresh purified water in purified water storage tank above L level and when water level in purified water tank goes above L level then distribution pump will start automatically.
- 6.16** After collecting fresh purified water, circulate this water in loop line for 15 minute and during circulation be ensuring that purified water level remains above LL level.



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- 6.17** After circulation flush out the tank and loop line drain out the collected purified water by drain valve.
- 6.18** Close the drain valve and fill the tank with fresh purified water.
- 6.19** Check the HH level sensor of purified water tank during operation, when water reaches to its HH level then purified water generation system will stop and when water level comes below the H level sensor then purified water generation system will operate automatically.
- 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** QC shall collect the sample as per request from engineering **Annexure – IV “Request for sample collection”**.
- 6.22** As per QC analysis report we release the water after intimation **Annexure- III “Intimation of Sanitization”**.
- 6.23** Frequency of the sanitization shall be one month \pm 7 days or whenever required.
- 6.24** Record the sanitization details as per **Annexure –II. “Purified Water System Sanitization Record”**.
- 6.25 Verification of purified water tank sensor:**
- 6.24.1** LL level sensor: When water level goes below the LL level then distribution pump will stop automatically.
- 6.24.2** L level sensor: When water level reaches above L level then distribution pump will start automatically.
- 6.24.3** HH level sensor: When water level reach to its HH level then purified water feeding valve will close and purified water generation will stop automatically.
- 6.24.4** H level sensor: When water level reach to H level then purified water feeding valve will open and purified water generation will start automatically.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure - I	Purified Water System Sanitization Schedule	
Annexure - II	Purified Water 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



PHARMA DEVILS

ENGINEERING DEPARTMENT

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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.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – I PURIFIED WATER 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
Executive / Officer Engineering
Sign & Date

Checked By
Head Engineering
Sign & Date

Approved By
Head QA
Sign & Date



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ANNEXURE – II
PURIFIED WATER SYSTEM SANITIZATION RECORD

AREA / BLOCK:

Loop No.:

Tank ID:

Pump ID:

Sanitization Done Date:

Sanitization Next Scheduled Date:

S.No.	Observation				
1.	Water collect for sanitization				
2.	Sanitization Start Time after achieving temp.(NLT 80°C) in return line				
3.	Tank Temp. (NLT 80 °C)				
4.	Return Loop Temp.(NLT 80°C)				
5.	Vent Filter Temp.				
6.	Temp. Reading After 15 min. of start time	Temp.(NLT 80°C)			
		Time			
7.	Flow Rate in return line				
8.	Sanitization End Time (After 1 Hour Circulation)				
9.	Low Low Level Sensor of PW Tank (Working/Not Working)				
10.	Low Level Sensor of PW Tank (Working/Not Working)				
11.	High Level Sensor of PW Tank (Working/Not Working)				
12.	High High Level Sensor of PW Tank (Working/Not Working)				

Remark:-

Done By (Engg.)
(Sign & Date)

Review By (Engg.)
(Sign & Date)

Verified By (QA)
(Sign & Date)

Note: - Frequency of Sanitization is One Month \pm 7 Days
Collect approximately 1600 Ltr. Water for 3 KL
Collect approximately. 3000 Ltr. Water for 5 KL



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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.



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ANNEXURE – IV
REQUEST FOR SAMPLE COLLECTION

Date:

From: Engineering Department

To: Quality Control Department

Name of the Sample:

Sampling point ID:

Intimation By:

Time:

Date & Sing:

Sr. 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.

