

PHARMA DEVILS ENGINEERING DEPARTMENT

Title: Sanitization of Purified and Distilled Water Loop				
SOP No.:	Revision No.:	00		
Effective Date:	Supersedes No.	Nil		
Review Date:	Page No.	1 of 5		

1.0 OBJECTIVE

The purpose of this SOP is:

1.1 To describe the procedure for sanitization of Purified and distilled water loop.

2.0 SCOPE

2.1 This SOP is applicable for the procedure for sanitization of Purified and distilled water loop.

3.0 RESPONSIBILITY:

- 3.1 The Maintenance Operator shall be responsible:
 - 3.1.1 Responsible for sanitization of Purified and distilled water loop.
 - 3.1.2 Responsible for maintaining the sanitization record.
- **4.2** The Maintenance Engineer shall be responsible:
 - **4.2.1** Responsible for ensure the proper sanitization.
 - **4.2.2** Responsible to take corrective action if any deviation observed.

4.0 ACCOUNTABILITY:

Head – Engineering Services



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5.0 **PROCEDURE:**

5.1STARTING PROCEDURE:

- 5.1.1 Before starting the sanitization, switch OFF the MCB of the feed pump,
- 5.1.2 Drain out the storage tank and water distribution line by opening the drain valve.
- 5.1.3 Close the drain valves.
- 5.1.4 Keep the zero dead leg valves at the user points closed.

5.1.5 Clean the SS flexible hose, which is being used to connect the pure steam generator and distribution loop with purified water for about ten minutes.

5.1.6 After cleaning of SS flexible hose, connect the pure steam line to distribution loop by flexible hose.

5.1.7 Start the pure steam generator, ref. SOP.

5.1.8 Allow to flow the pure steam through distribution loop and tank for about two hours.

5.1.9 After 2 hours, stop the pure steam generator.

5.1.10 Mean time, partially open all the user points one by one for ten minutes (approx) for passing the steam through the inter connecting pipe between the valve and machine.

5.1.11 Pass the Nitrogen Gas through the loop for cooling down the system to ambient temperature.

5.1.12 After that, Flush out the close loop and inter connecting pipes with purified water for about 30 minutes.

5.1.13 After flushing, close the zero dead valves (user points) and start the distribution loop. Ref. SOP.



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5.1.14 Keep the SS flexible hose properly rolled and closed at both ends for next sanitization.

FREQUENCY OF SANITIZATION: 5.2

5.2.1 Sanitization of Purified water loop to be carried out once in Month and Sanitization of WFI loop to be carried out once in Month.

6.0 **ANNEXURES:**

- : Sanitization record of purified water loop Annexure –I
- Annexure II : Sanitization record of WFI loop

8.0 **References** (S)

NIL

Glossary 9.0

SOP	:	Standard Operating procedure
No	:	Number
WFI	:	Water For Injection.
SS	:	Stainless Steel.





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Annexure I

SANITIZATION RECORD OF PURIFIED WATER LOOP

S.No.	Date of Sanitization	Sanitization Time		Sanitization	Remarks	Operator's Signature	Engineer's Signature
B .1 U .		From	То	Done By	Nellia 1KS	Signature	Signature





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Annexure II

SANITIZATION RECORD OF WFI LOOP

S.No.	Date of Sanitization	Sanitization Time		Sanitization	Remarks	Operator's	Engineer's Signature
5. INU.	Date of Samuzation	From	То	Done By	Kemarks	Signature	Signature