

PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering

TITLE: Passivation Of H	Pure Steam Generation And Distribution Syst	em	
SOP No.		Revision No.	
Effective Date		Supersedes No.	
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1.0 OBJECTIVE

The purpose of this SOP is:

1.1 The Objective of this SOP is to describe the procedure for Passivation of Pure Steam Generation and Distribution System.

2.0 SCOPE

2.1 This SOP is applicable for the procedure for Passivation of Pure Steam Generation and Distribution System. at

3.0 RESPONSIBILITY:

- **3.1** The Maintenance Operator shall be responsible:
 - 3.1.1 Responsible for Passivation of Pure Steam Generation and Distribution System.
 - **3.1.2** Responsible for maintaining the sanitization record.
- **3.2** The Maintenance Engineer shall be responsible:
 - **3.2.1** Responsible for assurance of proper sanitization of the plant.
 - **3.2.2** Responsible for take corrective action if any operational deviation observed.

4.0 ACCOUNTABILITY

Head – Engineering Services

4.1 PROCEDURE: PRIMARY CHECKS:

- **4.1.1** Before starting the Passivation, put the system in manual mode. And ensure that the power supplies for the instruments are 'OFF'
- **4.1.2** Drain out the Pure Steam Generator Column steam distribution line by opening the valves and then close it.



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- **4.1.3** Remove the conductivity sensor from the plant and close the sensor isolation valve.
- **4.1.4** Keep the point of use valves are open.
- **4.1.5** Disconnect the pure steam line from the stem sterilizers and connect the line to drain point.

4.2 CHEMICAL PREPARATION FOR NEW SYSTEM::

4.2.1 For Pure Steam Generation and Distribution System: Prepare 500 liters of 15%

concentrated nitric acid solution in purified water storage tank.

4.3 CHEMICAL PREPRATION FOR FURTHER APPLICATION:

4.3.1 For Pure Steam Generation and Distribution System: Prepare 500 liters of 15% concentrated citric acid solution in purified water storage tank.

4.4 STARTING PROCEDURE:

- **4.4.1** Start the boiler steam OR electrical heaters & heat the solution up to 60° C.
- **4.4.2** Take a fresh PVC flexible pipe and clean it with purified water and connect it with pure steam feed water line and WFI tank discharge line.
- **4.4.3** Start the feed water pump of Pure Steam Generator.
- **4.4.4** As soon as the Passivation solution started to come out from the point of use valves, then close all the valves. And stop the feed pump.
- **4.4.5** Keep the solution soak for three hours.
- **4.4.6** Then slowly throttle all point of use valves, and re start the feed pump.
- **4.4.7** Now the solution in the storage tank will slowly pass through the column and distribution line.
- **4.4.8** After completion of solution, stop the pump.
- **4.4.9** Take purified water into the storage tank and restart the feed pump for flushing of the entire system.



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4.4.10 Then open all point of use valves are fully and continue the final rinsing.

4.4.11 Take the water sample during rinsing, check the conductivity and pH. If it is same as feed purified water (conductivity-<1.2 ms/cm and pH 5-7), stop the rinsing. Otherwise keep the system in continuous rinsing till get pH and conductivity as specified.

4.4.12 Then refit the conductivity sensor.

4.4.13 Start the Pure Steam Generator as per Ref. SOP and take the Distribution system in service.

4.5 DISPOSAL OF CHEMICALS:

4.5.1 Passivation chemicals have to be disposed through ETP for further treatment.

4.6 FREQUENCY OF PASSIVATION:

4.6.1 Passivation of pure steam generation and distribution system to be carried out once in every

year. (Frequency is decided on the basis of manufacturer's recommendation).

5.0 ANNEXURES:

Annexure -I: Pure Steam Generation and Distribution System Passivation record.

7.0 **REFERENCES (S)**

Nil

8.0 GLOSSARY

SOP	:	Standard Operating procedure
No	:	Number



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		PURI	E STEAM (GENERA	TION AND D	ISTRIBUT	TION S	YSTEM P	ASSIVA	TION RECOR	RD			
S.No.	Passivation	Passivation	Passivation Time		me Passivation	Feed water	Final	Final rinse	Remarks	Operator's	Engineer's Sign.			
	Done on	Due on					solution	quali	ty	water q	uality		Sign.	
					temperature	~		~	1					
			From	То	(°C)	Con.	pH	Con.	DH D					
							-		P					
						(µs/cm)	•	(µs/cm)	P					
						(µs/cm)	-	(µs/cm)	P					
						(µs/cm)	-	(µs/cm)	P					
						(µs/cm)		(µs/cm)	P					
						(μs/cm)		(µs/cm)						