



Title: Passivation of Water System

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	1 of 4

1.0 OBJECTIVE:

To lay down a procedure for passivation of water system.

2.0 SCOPE:

This SOP is applicable for passivation of water system.

3.0 RESPONSIBILITY:

Officer/Executive – Engineering

4.0 ACCOUNTABILITY:

Head – Engineering

5.0 ABBREVIATIONS:

ER Engineering
HNO₃ Nitric Acid
Ltd. Limited
Pvt. Private
QC Quality Control
Qty Quantity
SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 Fill the Purified Water Storage tank up to the half level.

6.2 Ensure that Suction and Discharge Valve of pump are open and all user points & sampling valves are closed.

6.3 Start the recirculation pump and circulate water for 30min.

6.4 Drain the Water from the tank and Piping via user points & Sampling Valves.

6.5 Prepare Cleaning Solution by adding 2% of HNO₃ solution in Purified Water Storage tank.

6.6 Start the Circulation pump and circulate the Cleaning Chemical for 60min.

6.7 Solution Shall be Prepared in Purified Water, and Quantity of the Nitric acid shall be computed as:

$$Qty. \text{ of } HNO_3 = 100 * 2 / \% \text{ assay of the Solution}$$

6.8 Flush the Cleaning Chemical from the entire loop and tank via Sampling and User Points.

6.9 Prepare Passivation chemical by diluting Sodium Hydroxide (NaOH) of 100% purity with purified Water to make 2% of the solution tank.



PHARMA DEVILS

ENGINEERING DEPARTMENT

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SOP No.:		Revision No.:	00
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Review Date:		Page No.	2 of 4

- 6.10** Start the Recirculation pump & circulate the Passivation Chemical for 60min.
- 6.11** Drain the Passivation Chemical from the equipment's and Circulation loop via user Points and Sampling Points.
- 6.12** Transfer Fresh Purified Water to the Purified Water Storage Tank.
- 6.13** After this, flush the Purified Water till the pH is neutral (5.0 to 7.0) or to the in feed Water Quality.
- 6.14** **Frequency:** in case of any Modification, Discontinuation and New Installation.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Intimation Form	
Annexure-II	Log for Passivation of Purified Water Storage and Distribution System	

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:

As per Manual.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



Title: Passivation of Water System

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	3 of 4

ANNEXURE – I
INTIMATION FORM

FROM,

Engineering Department

SUBJECT: Passivation of Purified Water Storage and Distribution System

Date of Passivation :

S.No.	Department	Name	Remark	Signature & Date
1.	Quality Assurance			
2.	Production			
3.	Quality Control			

