STANDARD OPERATING PROCEDURE

Department: Engineering			
TITLE: Passivation of Equipments and Water System			
SOP No.		**Revision No.**	
Effective Date		**Supersedes No.**	
Review Date		**Page No.**	1 of 4

1.0 OBJECTIVE:

To lay down a Procedure for Passivation of Equipments and Water System.

2.0 SCOPE:

This SOP is applicable for passivation of Purified water system.

3.0 RESPONSIBILITY:

Executive/Officer- Engineering

4.0 ACCOUNTABILITY:

Department Head: Approval, Ensure Training and Implementation of this SOP's.

5.0 DEFINITION:

Passivation is the chemical treatment of a stainless steel with a mild oxidant, such as a nitric acid solution, for the purpose of enhancing the spontaneous formation of the protective passive film.

6.0 PROCEDURE:

Following procedure shall be followed for passivation of purified water system, equipments and WFI system.

6.1 **Initial flush:** The system is flushed thoroughly using purified water during the passivation of purified water system and equipments. System is flushed thoroughly using water for injection during the passivation of WFI system.

6.2 **Alkalinity flush:** The system is flushed with chemical Solution (1% NaOH w/v) for 1 hour.

6.3 **Second Flush**: The system is flushed through purified water to remove alkali from the system. Checking the pH of outlet and inlet water & ensure both pH should be equal.

6.4 **Passivation:** Passivation is carried out by filling and circulating Nitric acid solution 5% to 10% for 1 hour.

6.5 **Final Flushing:** The system is flushed with purified water to remove acid from the system during the passivation of purified water system and equipments. System is flushed thoroughly WFI

during the passivation of WFI system. Checking the pH of outlet and Inlet water & ensure both pH should be equal.

6.6 **Acceptance Criteria**: Checking the pH of outlet and Inlet water & ensure both pH should be equal.

7.0 ABBREVIATIONS:

No. Number

PW: Purified Water

QA: Quality Assurance

SOP Standard Operating Procedure

S. No. Serial Number

SP: Sampling Point

UP: User Point

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	pH of Sample	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department.
- Controlled Copy No. 01Engineering Department.
- Controlled Copy No. 02 Production.
- Controlled Copy No. 03 Quality Control Department.

10.0 REFERENCES:

In-House

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

STANDARD OPERATING PROCEDURE

Department: Engineering

TITLE: Passivation of Equipments and Water System

SOP No.		**Revision No.**	
Effective Date		**Supersedes No.**	
Review Date		**Page No.**	4 of 4

ANNEXURE–I

pH OF SAMPLE

S.No.	Date	Time	Name of Equipment/Line/Loop	pH of Inlet water	pH of Inlet water