PROTOCOL FOR VALIDATION OF CLEANING PROCEDURE AFTER SANITIZATION OF WATER SYSTEM

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1.0 PRE-APPROVAL:

The author signature indicates that this document has been prepared in accordance with existing cGMP standards and adequately reflects the task and deliverable necessary for validation of the equipment/instruments/system.

Prepared By/Function	Designation	Signature	Date
Quality Assurance			

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the adequacy of tasks and deliverables necessary for validation of the equipment/instrument/system and that the documentation and information included complies with current good manufacturing practices.

Reviewed By/Function	Designation	Signature	Date
Operations			

The approver's signature indicates that, this documentation and information contained herein complies with applicable regulatory, corporate, divisional/Departmental requirements and current good manufacturing practices.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			

PROTOCOL FOR VALIDATION OF CLEANING PROCEDURE AFTER SANITIZATION OF WATER SYSTEM

2.0 OVERVIEW

2.1 Objective:

The objective of this protocol is to establish the documental evidence to verify that the Purified Water System is sanitized and cleaned effectively and there are no residues of sanitizing agent in the system.

- Relevant Operating Procedures for the Purified Water System.
- Sanitization Procedure & Frequency for the sanitization.
- Estimation of chemical residues of sanitizing agent.

The sanitization of the system (Reverse Osmosis) is quarterly performed by using sanitization kit containing sanitizing agent. The study aims at qualitative estimation of residues of sanitizing agent, if any after cleaning of water system as per defined procedure. The validation of cleaning procedure/ cycle shall be performed by estimation of residues during the process of cleaning.

2.2 Scope:

This protocol shall be applicable to the Purified Water System installed.

This protocol shall cover responsibilities of different departments, system description, reference to documents and standard operating procedures, performance qualification study plan, deviation report, final report of the study with summary, conclusions & recommendations and documentation

3.0 REASON FOR QUALIFICATION:

Please tick the appropriate option (√):

New installation

Other (Please specify)

_____

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4.0 PREREQUISITES

S.No.	Description	Y / N/NA	Checked by	Date
1.	Sanitization kit available (Imunell BA 80)			
2.	Residue estimation of kit. (Imunell BA 80) available			
3.	Sanitizing agent residue testing procedure available			
4.	Training has been imparted to the concerned.			
5.	Sanitization procedure available			

Verified By: _____ **Date: _____**

5.0 EXPERIMENTAL PLAN & PROCESS.

5.1 System and Process Description:

The Labostar TWF is a validated water generating system providing purified water as per in-house specification. The system consists of components as pre-filtration unit, Reverse Osmosis, Polishing Module and UV-Oxidizer. System is sanitized quantitatively by using sanitization kit (Immunell BA 80) recommended by manufacturer. The sanitizing agent flows through the system covering polishing module and UV Oxidizer in a closed loop system (temporary for sanitization for about 1 hour) and then sanitizing agent is drained out and water circulates through the system. The auto removal is controlled by conductivity parameter. Once the conductivity is below the specification limit – pure water passes for 2 micron filtration. It is recommended to estimate the residues of sanitizing agent after pre-determined cleaning cycle after sanitization. Manufacturer of sanitizing agent has provided the information on analytical reagent /kit for estimation of sanitizing agent residues and procedure to follow.

To establish the effectiveness of cleaning after sanitization, the intermittent samples (15 minutes, 30 minutes, 45 minutes and 60 minutes) shall be taken to measure the degree of effectiveness of cleaning.

5.2 Procedure:

5.2.1 Objective: The objective of this study is to validate the cleaning procedure after sanitization.

5.2.2 Study Procedure / Approach:

5.2.2.1 After completion of sanitization, the sanitizing agent shall be drained out as per sanitization cycle. Then the cleaning procedure will start. The cleaning of the system shall be performed for 60 minutes. Once the cleaning cycle starts, the samples at interval of 15 minutes, 30 minutes, 45 minutes and 60 minutes shall be taken and tested with the test kit as per the General Procedure QCLNRB-GP-QA-001-00. The time at which complete removal of sanitizing agent is observed shall be determined and the time cycle designed (recommended) by manufacturer shall be validated.

5.3 Sampling and Analysis:

5.3.1 Sampling and analysis shall be performed as per General Procedure**.** Samples shall be collected at intervals of 15 minutes, 30 minutes 45 minutes and 60 minutes.

5.3.2 Cleaning study shall be carried out on the day of sanitization.

5.3.3 Water shall be released for its intended use after review and evaluation of test results.

5.3.4 Data shall be recorded in the format attached to this protocol as annexure - I: Cleaning Record.

5.3.5 After analysis is performed, the reports shall be prepared by QA.

5.3.6 QA shall then approve the specific duration required to rinse the purified water system after sanitization.

5.4 Results and Conclusion

5.4.1 On the basis of the results of samples at different intervals, the time at which there are no traces of residues is determined.

5.4.2 Study shall be concluded on the basis of establishment of complete removal of traces of sanitizing agent.

5.4.3 A summary report on analytical data and observations shall be prepared and annexed (annexure II), and also addressed in the final report point 8.

6.0 ACCEPTANCE CRITERIA

The sample collected after cleaning should have no traces of the sanitizing agent.

7.0 DEFICIENCY AND CORRECTIVE ACTION REPORT:

Description of deficiency and its classification*		
S.No.	**Deficiency**	**Category**

Recommended corrective action, Responsible person			
S.No.	**Recommended corrective action**	**Responsibility**	**Assigned date**

Provisional approval (If Applicable) to proceed further (For Category B Deficiencies):

Corrective actions taken (For Category C deficiency)			
S.No.	**Corrective action taken**	**Sign**	**Date**

Closure remarks: Allowed / Not allowed to proceed further

Verified and approved by Engineering:

Verified and approved by Quality Assurance:

Follow-up Compliance (For category B deficiency):

Recommended corrective actions taken (Action taken within stipulated period)			
S.No.	**Corrective action taken**	**Sign**	**Date**

Closure remarks:

*__Category A:__ Equipment accepted with deficiency

Category B: Conditional acceptance of equipment, deficiency to be corrected within stipulated period

Category C: Deficiency to be rectified before proceeding further

8.0 FINAL REPORT:

- **Summary**
- **Analysis *I* Evaluation of data**
- **Certification**

Summarized By: _____ Date_____

Reviewed By: _____ Date _____

9.0 REFERENCE DOCUMENTS:

S.No.	Title	Location
1.	Testing of Chemical Residue After Sanitization	Document Room

Reviewed By: _____ Date_____

10.0 ABBREVIATIONS:

S.No.	Abbreviation	Description
1.	UV	Ultra Violet

Reviewed By: _____ Date_____

11.0 ATTACHMENTS:

S.No.	Description
1.	Annexure-I: Cleaning Record
2.	Annexure- II: Summary Report

Reviewed By: _____ Date_____

12.0 POST APPROVAL:

This is hereby certified by the following functionaries that the equipment / instrument / system stands qualified for its intended purpose.

The reviewer's signature indicates that, this document has been Verified and it accurately and completely reflects the tasks and deliverables, necessary for validation of the facility and all associated equipment /instruments / systems and that the documentation and information included complies with applicable regulatory, corporate, divisional / departmental requirements and current Good Manufacturing Practices.

Verified By/ Function	Designation	Signature	Date
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory, corporate, division / departmental requirements and current Good Manufacturing Practices.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			

13.0 APPROVAL

(Follow Up Compliance for closure of category Type 'B' deficiency)

This is hereby certified by the following functionaries that the Type 'B' deficiency in equipment/instrument/system is closed.

Reviewed By/ Function	Designation	Signature	Date
Quality Assurance			

Approved By/ Function	Designation	Signature	Date
Quality Assurance			

PROTOCOL FOR VALIDATION OF CLEANING PROCEDURE AFTER SANITIZATION OF WATER SYSTEM

ANNEXURE I

CLEANING RECORD

Date:					
Control Sample Prepared Yes ☐ No ☐				Colorless Observed Yes ☐ No ☐	
S.No.	Time	Color observed (Tick where applicable)		Conforms to control sample (Tick where applicable)	
		Colorless	Pink	Yes	No

	Performed By (QA)	Approved By (QA)
Name:		
Designation:		
Sign and Date:		

Annexure II

SUMMARY REPORT:

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Prepared by
Sign & Date:

Reviewed By
Sign & Date: