



Title: Operation of Ultrapure Water System

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1. PURPOSE:

To lay down a procedure for sampling and testing of Purified Water.

2. SCOPE:

This procedure is applicable for sampling and testing of Purified Water in Quality Control department.

3. RESPONSIBILITY:

Officer/Executive-Quality Control

4. ACCOUNTABILITY:

Head – QC Department

5. PROCEDURE:

1.0 Sampling Procedure for Chemical Analysis

1.1 Clean and dried Flasks/ Bottle shall be taken for sampling of purified water.

1.2 Before collecting the Purified water, flask/bottle shall be rinsed twice with about 200 ml sample and 1000 ml sample of purified water shall be collected for chemical analysis.

2.0 Sampling Procedure for Microbiological Analysis

2.1 Bottle Preparation

2.1.1 The required number of wide mouth bottles having screw caps or conical flasks with cotton plugs shall be taken for sampling of Purified water.

2.1.2 The bottles/flasks shall be kept in the autoclave and the bottles/flask shall be sterilized by operating the autoclave as per Cycle No.4 (Validated cycle for G & C sterilization).

2.1.3 After completion of sterilization cycle, the Door 2 of the autoclave shall be opened from the buffer room side and the bottles shall be taken out from the autoclave.

2.1.4 The bottles shall be cooled to Room Temperature. After cooling, the bottles shall be used for sampling.

2.2 Sampling

2.2.1 Label the sample container with Sampling Location, sampling point No., date, time and sampled by as shown in the label as per Clause 5.0.

2.2.2 The sampling port of source water sampling point shall be opened and allowed to drain for 2 min.



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2.2.3 The bottle/ flask shall be taken near the sampling port and the cap/ cotton plug shall be opened. The Sample (about 200ml) shall be collected and immediately the cap / cotton plug shall be closed tightly.

2.2.4 After sampling the Purified water shall be brought to the laboratory for analysis.

2.2.5 The sample shall be analysed within 1 hour. If the sample is not analysed then the sample shall be stored at 2-8°C and analysed within 8 hours.

3.0 Testing of Purified Water

3.1 The inspection lots generated by SAP system shall be entered in the Water sample inward register as per Annexure –V of SOP. If extra lot has been generated, the lot shall be cancelled and the required sampling point shall be generated by “Manual call” in the SAP system.

3.2 Chemical and Microbiological testing shall be done for the Purified water as per purified water Specification. For Liquid / Tablet Facility, DM Unit outlet and Return loop shall be collected and sampled daily and the other User points shall be sampled and analysed as per Purified water sampling plan Annexure- I.

3.3 Purified Water shall be checked for pH, Conductivity parameters and the information shall be given for the usage of Purified Water to the production Annexure - VI.

3.4 Results shall be recorded in the Purified Water Worksheet Annexure – III and punching of User Decision (UD) shall be punched in SAP system after complete analysis of Purified Water.

3.5 Analytical Test Report, Annexure -IV shall be attached with the TDS.

3.6 Trends shall be prepared on yearly basis.

3.7 Chemical and Microbiological testing shall be done for the Purified water as per purified water specification. For External Preparation facility the EDI Unit outlet and Return loop shall be sampled and analysed daily and the other points shall be covered once in a week as per Annexure –II.

3.8 Purified Water shall be checked for pH, Conductivity parameters and the information shall be given for the usage of Purified Water to production as per Annexure - VI.

3.9 The results shall be recorded in Purified Water Worksheet Annexure – III.

3.10 The Analytical Test Report, Annexure -IV shall be attached with the purified water work sheet

3.11 Trends shall be prepared on Quarterly basis.

3.12 If there is a breakdown in TOC, the alternate test, Oxidisable Substances shall be performed.



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3.13 The Purified water used in Microbiology Wash room shall be analysed for microbial load once in a month.

4.0 Total Aerobic Microbial Count:

Acceptance Criteria: Not More Than 100 CfU / ml

Action Limit: More Than 60 cfu/ml **Alert Limit:** More Than 40 cfu/ml

5.0 Label for sampling containers

Name of sample	:
Sampling Location:	
Sampling point No:	
Date/Time	:
Sampled by	:

ANNEXURE(S):

Annexure I: Purified Water Sampling Points of Liquid / Tablet Facility and Schedule.

Annexure II: Purified Water Sampling Points of External Preparation Facility and Schedule.

Annexure III: Purified Water Worksheet

Annexure IV: Analytical Test Report - Purified Water

Annexure V: Water sample Inward register.

Annexure VI: Information for Purified Water Usage.

REFERENCES:

Indian Pharmacopoeia,

British Pharmacopoeia,

United States Pharmacopoeia and European Pharmacopoeia.