Title: Sampling Procedure for Water Samples

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1.0 Objective

To lay down a general procedure for Sampling of Raw water, Soft water, Treated water and Purified water samples for Chemical and Microbiological analysis.

2.0 Scope

This SOP is applicable to pharmaceutical formulation plant.

3.0 Responsibility

Microbiologist/ QC-Officer : Responsible for sampling of water from different user points.

Head-QC/Designee : Responsible for compliance of the SOP.

4.0 Abbreviations & Definitions

SOP : Standard Operating Procedure

QC : Quality Control

QA : Quality Assurance

IPA : Isopropyl Alcohol

5.0 Procedure

5.1 Sampling for Chemical Analysis

5.1.1 Take clean and dried 1000 ml transparent glass bottles.

5.1.2 Before collecting the water sample, drain out the water from the tap for about two to three minutes.

5.1.3 Open the sampling bottle by removing the stopper.

5.1.4 Rinse the sampling bottle two to three times with the water to be sampled.

5.1.5 Collect the water sample till it overflows and close the stopper.

5.1.6 Affix appropriate label on the bottle after sampling with details like type of water, sampling point code, date of sampling and sampled by as per the Annexure-2.

5.1.7 Take the sample for analysis in chemical laboratory.

5.1.8 Analyze the sample as per the established test procedures and specifications.

5.1.9 Frequency of sampling shall be as per Annexure-1.(After completion of phase 1 &2)

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5.1.10 A.R.No. of respective sample to be informed to QA and Production Department.

5.2 **Sampling for Microbial Analysis**

5.2.1 Take 500ml capacity of colour less sampling bottles, Close the mouth of bottles properly with stopper and wrap it with aluminum foil. Sterilize the bottles at 121°C to 124°C, 15 to 18 lbs pressure for 30 minutes.

5.2.2 Wear nose mask and gloves and sanitize hands with 70 % v/v IPA prior to sampling.

5.2.3 Before collecting the sample drain out the water from sampling point for approximately 2-5 minutes (i.e. 2 to 5 liters of water to be drained out).

5.2.4 Clean the outside of the mouth of the sampling point with the cotton plug wet with 70% IPA and allow to dry then collect the sample from sampling point.

5.2.5 Label the sample bottle as per the Annexure-2.

5.2.6 Take the sample to the microbiology laboratory for analysis.

5.2.7 Analyse the sample within 1 hour after collecting the sample, alternatively keep the sample in refrigerator at 2°C to 8°C for 6 hours.

5.2.8 Allow the sample to attain the room temperature before analysis if it is kept in refrigerator.

5.3 **Sampling Plan**

5.3.1 Sampling of different types of water shall be done as per the Annexure-1.

6.0 Forms and Records

6.1 Water Sampling Plan : Annexure-1

6.2 Sample Label : Annexure-2

7.0 Distribution

7.1 Master Copy : Documentation cell (Quality Assurance)

7.2 Controlled Copies : Quality Control, Quality Assurance

8.0 History

Date	Revision Number	Reason for Revision