



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Sampling and Monitoring of Water System

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 5

1.0 OBJECTIVE

To lay down procedure for sampling and monitoring of water system.

2.0 SCOPE

This SOP is applicable for sampling and monitoring of water system.

3.0 RESPONSIBILITY

Prepared by - Executive Quality Control

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Types of water and sampling quantity of water

4.1.1 Types of water samples to be collected for analysis are mentioned in table - I.

Table - I

Type of Water
Potable Water
Purified Water
Water for Injection
Pure Steam Condensate

4.1.2 Collect sufficient number of sample bottles according to the sampling schedule.

4.1.3 Depyrogenate all sample bottles in dry heat sterilizer at suitable temperature for sufficient time to collect samples for Bacterial Endotoxin testing.

4.1.4 Take stopper glass bottles to collect the water sample for Total Organic Carbon analysis.

4.1.5 The bottle must be cleaned with cleaning agent, rinsed with purified water and dried in oven for suitable temperature for sufficient time.

4.1.6 Sterilize the glass bottles/ scotch drams bottles in moist heat sterilizer at sufficient temperature for sufficient time for collection of samples for testing of microbial analysis.

4.1.7 For the collection of treated raw water prepare sterile 3% Sodium thiosulphate.



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- 4.1.8 Take steam sterilized sample bottles to LAF and discard the water from that bottle and add 0.1ml of sterile 3% Sodium thiosulphate and cap the bottle tightly.
- 4.1.9 Mark this bottle especially for microbial sampling of treated raw water.
- 4.1.10 Make the required number of sampling bottles ready.
- 4.1.11 Ensure that all the bottles are properly capped and bottles are segregated as per the requirement of water sampling.
- 4.1.12 Collect all the sufficient bottles and go to the sampling sites for sampling.
- 4.1.13 Sample of water to be collected for analysis are mentioned in table - II.

Table - II

Sampled for analysis	Quantity to be sampled for analysis
Chemical Analysis	1000 mL in non sterile glass bottle
TOC/ Oxidisable substances	100ml non sterile TOC bottle
Microbiological Analysis	250 mL purified water in sterile bottle 250 mL potable water in sterile bottle 250 mL chlorinated water in sterile bottle containing 0.1ml of 3% Sodium thiosulphate 500 mL water for water for injection and Pure steam condensate in sterile bottle
Bacterial Endotoxin Testing	10 mL in depyrogenated glass bottles

4.2 Prerequisites

- 4.2.1 Before sampling ensure that the sampling points are properly identified.
- 4.2.2 Before sampling water generation system should be under operation.
- 4.2.3 Before sampling storage tanks and distribution loops should be under recirculation.
- 4.2.4 Fully open the valve of sampling point/ user point.
- 4.2.5 Drain the water for about 2 minute.

4.3 Collection of water sample for microbiological analysis

- 4.3.1 Bring the sample bottle near the sampling point.
- 4.3.2 Hold the bottle from the base and slowly open the cap. (Take precaution not to touch mouth of the bottle).



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4.3.3 Do not rinse the sampling bottle while sampling for microbiological analysis.

4.3.4 Collect the water sample as per table - II.

4.3.5 After collecting the sample screw cap the bottle tightly.

4.4 Collection of sample for TOC Analysis

4.4.1 Open the bottle specified for the sampling.

4.4.2 Rinse the bottle with at least 3 times with water to be sampled.

4.4.3 Discard the rinsate.

4.4.4 Fill the sample with out leaving any air space and cap it immediately.

4.4.5 Collect the water sample as per table - II.

4.5 Collection of sample for Chemical Analysis

4.5.1 Hold the sampling bottle at bottom and open the cap.

4.5.2 Rinse the bottle for at least thrice with the sampled water.

4.5.3 Collect the sample in bottle without leaving air space specified for chemical analysis.

4.5.4 Collect the water sample as per table - II.

4.6 Collection of sample for Bacterial Endotoxin Testing

4.6.1 Hold the sampling bottle from the neck and remove the stopper and collect the sample specified for Bacterial Endotoxin testing.

4.6.2 Collect the water sample as per table - II.

4.6.3 After collecting the sample screw cap the bottle tightly.

4.6.4 Label the sampling bottles for monitoring of water as per Annexure - I.

4.6.5 After sampling bring the samples to the laboratory for analysis.

4.6.6 In case of microbiological analysis if the samples are not to be tested within 6 hours of sampling, keep the samples in the refrigerator at 2 to 8°C.

4.6.7 Testing should not be delayed beyond 24 hours of sampling.

4.6.8 Follow the Standard test procedure for testing of potable water, purified water, water for injection and pure steam condensate.



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5.0 SAFETY & PRECAUTIONS

- 5.1 Always use hand gloves and nose mask for sampling of microbiological analysis.
- 5.2 Disinfect the palms with 70% IPA.
- 5.3 Use thermal resistant gloves for sampling of water for injection and pure steam condensate.

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

7.0 REFERENCES

Not applicable.

8.0 ABBREVIATIONS

- SOP : Standard Operating Procedure
- TOC : Total Organic Carbon
- IPA : Iso Propyl Alcohol
- % : Percentage
- °C : Degree Centigrade

9.0 ANNEXURES

- Annexure - I** : Water sampling label



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ANNEXURE - I WATER SAMPLING LABEL

Water Sampling Label

Sample For: _____

Sampling Point: _____

Sampled By: _____

Sign: _____

Date: _____