



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Procedure for Sampling of Water for Microbiological and Chemical Analysis	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down a procedure for sampling of water for microbiological and chemical analysis.

**2.0 SCOPE:**

This SOP is applicable for sampling of water for Microbiological and Chemical analysis.

**3.0 RESPONSIBILITY:**

Officer / Executive - Microbiology

**4.0 ACCOUNTABILITY:**

Head – QC

**5.0 ABBREVIATIONS:**

IPA	Isopropyl Alcohol
Ltd.	Limited
LCD	Liquid Crystal Display
ML	Microbiology Laboratory
MLT	Microbial limit test
NA	Not Applicable
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

**6.0 PROCEDURE:**

**6.1 Pre-Requisition for Water Sampling:**

S.No.	Requirements
1.	Sterilized Sampling Bottles
2.	Sterilized Hand Gloves
3.	Tong
4.	Depyrogenated Sampling Bottles/Vials
5.	SS Container
6.	Stop Watch
7.	70% IPA Filtered with 0.22 µ filter
8.	Heat Resistant Gloves



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### 6.2 Procedure for Microbiological Sampling:

#### 6.2.1 Sampling Procedure for Raw Water:

- 6.2.1.1 Sterilize all sampling bottles as per SOP titled "Operation and Cleaning of Double Door Steam Sterilizer". For sampling of raw water add 0.1 ml of 5% Sodium Thiosulphate Solution in bottle before sterilization.
- 6.2.1.2 Label all the bottles with sampling point date and Keep the sampling bottles in clean SS Container mopped with 0.22  $\mu$  filtered 70% IPA. Transfer the ss container along with the Sampling bottles to place of sampling, wear gloves and sanitize the hands with 0.22  $\mu$  filtered 70% IPA.
- 6.2.1.3 Open the sampling point and drain water for approximately 01 minute from specific sampling point.
- 6.2.1.4 Open the sampling bottle and carefully collect approximately 250 ml of sampled water and close the bottle immediately to avoid any external contamination close the sampling point and keep all sampled bottles in SS container and transfer to microbiology lab for further analysis.

#### 6.2.2 Sampling Procedure for Purified Water:

- 6.2.2.1 After sterilization labeled all the bottles with sampling point and date. Keep the sampling bottles in clean SS container mopped with 0.22  $\mu$  filtered 70% IPA. Transfer the SS container along with the sampling bottles to place of sampling, wear gloves and sanitize the hands with 0.22  $\mu$  filtered 70% IPA.
- 6.2.2.2 Open the sampling point and drain water for approximately 1 minute from specific sampling point.
- 6.2.2.3 Open the sampling bottle and carefully collect approximately 250 ml water sample and close the Bottle immediately to avoid any external contamination. Close the sampling point and keep all bottles in SS container and transfer to Microbiology Lab for further analysis.

#### 6.2.3 Sampling Procedure for Water for Injection and Pure Steam :

- 6.2.3.1 After sterilization; label all the bottles with sampling point and date. Keep the sampling bottles in clean SS container mopped with 0.22  $\mu$  filtered 70% IPA. Transfer the SS container along with the sampling bottles to place of sampling, wear gloves and sanitize the hands with 0.22  $\mu$  filtered 70% IPA.
- 6.2.3.2 Open the sampling point and drain water for approximately 30 second from specific sampling point; open the sampling bottle and carefully collect approximately 250 ml of sampled water and close the bottle immediately to avoid any external contamination. Collect approximately 10 ml sample for Bacterial Endotoxin test in separate 10 to 20 ml depyrogenated vial. Close the sampling point and keep all bottle and vial in SS container and transfer to microbiology lab for further analysis.



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**6.2.3.3** If it is not possible to test the sample within about 2 hours of collection, the sample should be held at refrigerated temperature (2-8°C) for a maximum of about 12 hours to maintain the microbial attributes until analysis.

### 6.3 Procedure for Chemical Sampling:

**6.3.1** Labeled all the bottles with sampling point and date. Keep the sampling bottles in clean SS container mopped with 0.22 μ filtered 70% IPA. Transfer the SS container along with the sampling bottle to place of sampling and wear gloves.

**6.3.2** Open the valve of specified sampling point and allow the water to flow for at least 1-2 minute.

**6.3.3** Rinse the bottle 3 times with the specified water sample and collect approximately 500 ml for purified water and water for injection and 1000 ml for raw water sample for chemical analysis.

**6.3.4** For TOC analysis; collect the sample in the 100 ml bottle.

**6.3.5** The bottle should be filled up to brim & shall be free from air bubble.

**6.3.6** Rinse the stopper and close the bottle immediately.

**6.3.7** Follow the same sampling procedure for all sampling points for procuring water samples and bring the sampled water bottles to quality control laboratory for chemical analysis.

**6.3.8** Analyze the water samples after sampling. In case of hot water allow it to cool before analysis.

**6.3.9** If any sampling of water not perform as per sampling schedule due to any reason; same sampling point shall be done ±1 day of scheduled date.

### 6.4 Allotment of Analytical Report Number for Water Samples:

AR Number for Water Samples:

**W20240821001**

**Where,**

W	For Water
2024	Year
08	Month
20	Date
001	Increasing serial number 001, 002, 003 etc.

### 6.5 Frequency:

**6.5.1** Refer the Water Sampling Schedule.

**6.5.2** Record the Sampling Details in **Annexure-I**, Titled **“Water Sampling Log Book”**.



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**7.0 ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Water Sampling Log Book	

**ENCLOSURES:** SOP Training Record.

**8.0 DISTRIBUTION:**

- Controlled Copy No. 01                      Quality Assurance
- Controlled Copy No. 02                      Microbiology
- Master Copy                                      Quality Assurance

**9.0 REFERENCES:**

- USP Chapter Number 1231 “Water for Pharmaceutical Purpose”.
- SOP titled “Operation and Cleaning of Double Door Steam Sterilizer”.

**10.0 REVISION HISTORY:**

**CHANGE HISTORY LOG**

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

