



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Procedure for Sampling of Water for Microbiological Analysis	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for sampling of water for microbiological analysis.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

5.1 SAMPLING PROCEDURE FOR RAW WATER:

5.1.1 Sterilize all Sampling Bottles at 121°C for 30 min.

5.1.2 After sterilization label all the Bottles with Sampling Point, Date, Sampled By and Location. Keep the Sampling Bottles in clean SS Container mopped with 0.2 μ filtered 70% IPA.

5.1.3 Transfer the SS Container along with the Sampling Bottles to place of Sampling, wear gloves and sanitize with 0.2 μ filtered 70% IPA.

5.1.4 For sampling of Raw Water, Open the Sampling Point and Drain water for approx two minutes from Specific Sampling Point and then sample Raw Water.

5.1.5 Open the Sampling Bottle and carefully collect approximately 250 ml of Sampled Water up to the brim of bottle 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.

5.2 SAMPLING PROCEDURE FOR REVERSE OSMOSIS (RO) WATER AND PURIFIED WATER:

5.2.1 After sterilization label all the Bottles with Sampling Point, Date, Sampled By and Location. Keep the Sampling Bottles in clean SS Container mopped with 0.2 μ filtered 70% IPA.

5.2.2 Transfer the SS Container along with the Sampling Bottles to place of Sampling, wear gloves and sanitize with 0.2 μ filtered 70% IPA.

5.2.3 For sampling of Reverse osmosis (RO) and Purified Water, Open the Sampling Point and Drain water for approx one minute from Specific Sampling Point and then sample water.



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5.2.4 Open the Sampling Bottle and carefully collect approximately 250 ml of Sampled Water up to the brim of bottle 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.

5.3 SAMPLING PROCEDURE FOR WATER FOR INJECTION:

5.3.1 After sterilization label all the Bottles with Sampling Point, Date, Sampled By and Location. Keep the Sampling Bottles in clean SS Container mopped with 0.2 μ filtered 70% IPA.

5.3.2 Transfer the SS Container along with the Sampling Bottles to place of Sampling, wear gloves and sanitize with 0.2 μ filtered 70% IPA.

5.3.3 For sampling of water for injection, Open the Sampling Point and Drain water for approx thirty seconds from Specific Sampling Point and then sample water. Open the Sampling Bottle and carefully collect approximately 250 ml of Sampled Water up to the brim of bottle and close the Bottle immediately to avoid any external contamination. Collect approximately 10 ml sample for Bacterial Endotoxin test in separate 20 ml depyrogenated vials. Close the Sampling Point and keep all bottles and vial in SS Container and Transfer to Microbiology Lab for further analysis.

5.3.4 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.

5.4 FREQUENCY:

S.No.	TYPES OF WATER	SAMPLING FREQUENCY
1.	Purified Water (All Return Loops)	Daily
2.	WFI (All Return Loops)	Daily
3.	WFI (other than Return Loops)	Weekly
4.	Purified Water (Other than Return Loops)- I Block	Weekly
5.	Purified Water (Other than Return Loops)- General Block	Fortnight (Once in 15 days)
6.	Raw Water (All Points)	Monthly

5.5 Refer the **Annexure-II**, Titled “**Water Sampling Schedule for Microbiological Analysis**” for water sampling schedule.

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

6.0 REFERENCES:

USP – 37 Chapters 1231 General Information.



PHARMA DEVILS

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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Water Sampling Log Book	
Annexure-II	Water Sampling Schedule for Microbiological Analysis	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Quality Control Department
- Master Copy Quality Assurance Department

9.0 ABBREVIATIONS:

IPA	Isopropyl Alcohol
Ltd.	Limited
LCD	Liquid Crystal Display
MLT	Microbial limit test
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	New SOP	Nil	Nil	Nil



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ANNEXURE – II WATER SAMPLING SCHEDULE FOR MICROBIOLOGICAL ANALYSIS

Location	Sampling Point Location	Sampling Point ID No.	Frequency						
			Mon	Tue	Wed	Thu	Fri	Sat	Sun

* Sample will be collected when Softener I/II in operating condition.

F	- Fortnight
W	- Weekly
D	- Daily
M	- Monthly

Prepared By:

Checked By:

Approved By:

Officer/Executive-QC
(Sign & Date)

Manager-QA
(Sign & Date)

Head QA
(Sign & Date)