



Title: Sampling of Raw Water, Process Potable Water, Purified Water And Water For Injection / Pure Steam For Microbiological Analysis

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	1 of 4

1.0 OBJECTIVE:

To lay down a procedure for Sampling of Raw Water, Process Potable Water, Purified Water and Water for Injection / Pure Steam for Microbiological Analysis.

2.0 SCOPE:

This SOP is applicable for Sampling of Raw Water, Reverse Osmosis (RO) Water, Purified Water and Water for Injection /Pure Steam for Microbiological Analysis IN Microbiology Lab. of Quality Control at

3.0 RESPONSIBILITY:

3.1 Officer / Executive – QC (Microbiologist)

4.0 ACCOUNTABILITY:

4.1 Head – QC

5.0 DEFINITION:

6.0 PROCEDURE:

6.1 SAMPLING PROCEDURE FOR RAW WATER:

6.1.1 Sterilize all Sampling Bottles at 121°C for & 15 lbs or psi..

6.1.2 After sterilization label all the Bottles with Sampling Point, Date of Sampling. Keep the Sampling Bottles in clean SS Container mopped with 0.2 μ filtered 70% IPA.

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

6.1.4 For sampling of Raw Water, Open the sampling point valve and approx 1.0 liter water should be drain before sampling at each sample point.



Title: Sampling of Raw Water, Process Potable Water, Purified Water And Water For Injection / Pure Steam For Microbiological Analysis

SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	2 of 4

6.1.5 Collect approximately 250 ml of 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.

6.2 SAMPLING PROCEDURE FOR REVERSE OSMOSIS WATER AND PURIFIED WATER:

6.2.1 Sterilize all Sampling Bottles at 121°C & 15 lbs or psi..

6.2.2 After sterilization label all the Bottles with Sampling Point, Date of Sampling. Keep the Sampling Bottles in clean SS Container mopped with 0.2 μ filtered 70% IPA.

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

6.2.4 For sampling of Reverse osmosis (RO) and Purified Water, Open the sampling point valve and approx 1.0 liter water should be drain before sampling at each sample point.

6.2.5 Collect approximately 250 ml of 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.

6.3 SAMPLING PROCEDURE FOR WATER FOR INJECTION / PURE STEAM:

6.3.1 Sterilize all Sampling Bottles at 121°C & 15 lbs or psi.

6.3.2 After sterilization label all the Bottles with Sampling Point, Date of Sampling. Keep the Sampling Bottles in clean SS Container mopped with 0.2 μ filtered 70% IPA.

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

6.3.4 For sampling of water for injection, Open the sampling point valve and approx 1.0 liter water should be drain before sampling at each sample point.

6.3.5 Collect approximately 250 ml of 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.

6.3.6 For sampling of pure steam sterilized silicone tube shall be used for sampling.



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SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	3 of 4

- 6.4** 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.
- 6.5** In case of Sampling of water from CIP/SIP and Vial/Ampoule washing area, sample shall be collected through opening the clamp of water line and after sampling close the clamp carefully.
- 6.6** Record the Sampling Details in **Annexure-I**, Titled “**Water Sampling Log Book**”.
- 6.7** Water sampling schedule for routine & at validation shall refer as per SOP.

7.0 ABBREVIATIONS:

- °C Degree Celsius
- A. R. No. Analytical Reference Number
- CIP Clean In Place
- IPA Isopropyl Alcohol
- Ltd. Limited
- min. Minutes
- ml Milliliter
- No. Number
- QA Quality Assurance
- QC Quality Control
- RO Reverse Osmosis
- S.No. Serial Number
- Sign Signature
- SIP Sterilization In Place
- SOP Standard Operating Procedure
- SS Stainless Steel



PHARMA DEVILS

ENGINEERING DEPARTMENT

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SOP No.:		Revision No.:	00
Effective Date:		Supersedes No.	Nil
Review Date:		Page No.	4 of 4

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Water Sampling Log Book	
Annexure-II	Water Sampling Schedule (Routine Sampling)	
Annexure-III	Water Sampling Schedule (During Periodic Qualification)	

9.0 DISTRIBUTION:

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

10.0 REFERENCES:

- USP – 35 Chapters 1231 General Information.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		