



Title: Water Sampling for Chemical Analysis and Trend Preparation

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1.0 OBJECTIVE:

To lay down a Procedure for Water Sampling for Chemical Analysis and Trend Preparation.

2.0 SCOPE:

This SOP is applicable for Water Sampling for Chemical Analysis and Trend Preparation in
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3.0 RESPONSIBILITY:

Officer / Executive – QC

4.0 ACCOUNTABILITY:

Head – QC

5.0 DEFINITION: Not applicable

6.0 PROCEDURE

6.1 SAMPLING PROCEDURE:

- 6.1.1** Clean the suitable volume capacity (500ml,) Bottles with Tap Water and rinse with 2% Nitric Acid
- 6.1.2** Remove the cleaning agent by washing with Tap Water.
- 6.1.3** Final Rinse with Purified Water for remove complete residue.
- 6.1.4** Dry the bottle at 60 °C Temperature for 1.0 hour.
- 6.1.5** Affix Sticker Label on all the bottles as per Sampling Point.
- 6.1.6** Open the sampling point valve and approx. 1.0 liter water should be drain before sampling at each sample point.
- 6.1.7** Rinse the sampling container at least one time and carefully collect the required quantity of water sample for Analysis.
- 6.1.8** Do not fill the Water Samples in bottles up to the Brim.
- 6.1.9** Leave at least 6-8 mm Headspace between Water Level and Bottle Cap.
- 6.1.10** Rinse cap of Bottle and Cover with Aluminum Foil up to the neck.



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- 6.1.11** 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.
- 6.1.12** Analyze the conductivity test parameter immediately after collection; in case of Hot Water allow it to cool before analysis.
- 6.1.13** If analysis not done within 6 hours, sample shall be discard and again resample for specific sample points.
- 6.1.14** In case of sampling point connected with hosepipe, sample shall be collected after removal of hosepipe.
- 6.1.15** 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.
- 6.1.16** Water sampling quantity is 500 ml in purified water and water for injection, pure steam, Raw water.
- 6.1.17** Record the details of sampling in **Annexure-I**, Titled **“Water Sample Receipt / Inward Register**.

6.2 TREND PREPARATION FOR WATER SYSTEM:

- 6.2.1** Water analysis results trend shall be prepared for Water for injections, Purified water, Soft water, and Ultra filtration outlet water.
- 6.2.2** Trend shall be prepared on monthly basis of daily sample point for water analysis as per schedule.
- 6.2.3** Trend shall be prepared only for numeric results.
- 6.2.4** Weekly, fortnightly & monthly sample point trend shall prepared on yearly basis or whenever required.
- 6.2.5** Trend of after analysis results shall be prepared by using excel sheet as **Annexure-II**, Titled **“Trend of Water Analysis Results”**.
- 6.2.6** Excel sheet shall be password protected.
- 6.2.7** Excel sheet shall be prepared on monthly basis in a specific drive as below details:



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6.2.8 Used three alphabets of month & last two digit of current year like as for January used jan17.

6.2.9 Monthly trend shall be prepared in first week of next month.

6.2.10 Trend of after analysis results shall be prepared by Officer/Executive QC, Checked by Manager QC & finally approved by Head QC.

6.2.11 Water analysis shall be performance as per below STP NO:

6.2.11.1 Water for Injection: STP Titled “Chemical Analysis of Water for Injection.

6.2.11.2 Pure Steam: STP Titled “Chemical Analysis of pure steam.

6.2.11.3 Raw, Soft, Reverse Osmosis: STP Titled “Chemical Analysis of Raw Water, Soft Water, RO Water and Purified Water”.

7.0 ABBREVIATIONS:

°C	Degree Celsius
A. R. No.	Analytical Report Number
CIP	Clean In Place
DPI	Dry Powder Injection
ID No.	Identification Number
Inj.	Injection
LV	Liquid vial
Ltd.	Limited
ml	Milliliter
mm	Millimeter
No.	Number
QA	Quality Assurance
QC	Quality Control
S. No.	Serial Number
Sign	Signature
SIP	Sterilization In Place
SOP	Standard Operating Procedure
WFI	Water for Injection



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8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Water Sample Receipt / Inward Register	
Annexure-II	Trend of Water Analysis Results	

9.0 DISTRIBUTION:

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

10.0 REFERENCES:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change control no.	Details of Changes	Reason for Change	Effective Date	Done by
00	NA	NA	New SOP		



PHARMA DEVILS

ENGINEERING DEPARTMENT

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ANNEXURE-II TREND OF WATER ANALYSIS RESULTS



Remark: Trend of water analysis results comply/doesn't comply.

	Prepared By (Officer/Executive QC)	Checked By (Manager QC)	Approved By (Head QC)
Sign			
Date			