



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Chemical Analysis of Water for Injections and Pure Steam Condensate	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Chemical Analysis of Water for Injections and Pure Steam condensate.

2.0 SCOPE:

This SOP is applicable for Chemical Analysis of Water for Injections and Pure Steam condensate.

3.0 RESPONSIBILITY:

Officer / Executive – QC

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

IH	In-House
ml	Milliliter
No.	Number
NMT	Not More Than
PPB	Parts Per Billion
PPM	Parts Per Million
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

Prerequisite for chemical analysis of Water for Injections and Pure steam condensate

S.No.	Requirements
1.	Water sample for Chemical analysis
2.	Glass test tubes with stand
3.	Evaporating disk
4.	Graduate beaker with 01 ml to 200 ml marking
5.	Graduate Pipette (01 ml, 02 ml, 05ml, 10 ml)



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S.No.	Requirements
6.	Bulk Pipette (01 ml,02 ml,05ml,10 ml)
7.	Beaker 50 ml
8.	Small necessler cylinder
9.	Conical flask (250 ml)
10.	Measuring cylinder
11.	Burette and Burette stand
12.	Calibrated stop watch
13.	Calibrated Water bath
14.	Hot plate
15.	Calibrated pH meter, conductivity meter, analytical balance
16.	Calibrated Total Organic Carbon Equipment
17.	Calibrated UV Spectrophotometer
18.	Bubbler

Water for Injections / Pure Steam condensate sampling perform as per SOP, "Procedure for sampling of water for microbiological and chemical analysis" and perform the following tests as applicable.

6.1 DESCRIPTION: Transfer 15-20 ml of Water for Injections/Pure Steam condensate sample in a cleaned and dry test-tube and observe for clarity, colour and odour.

Acceptance Criteria: Clear, colourless and odourless liquid.

6.2 pH: Take about 25 ml of Water For Injections/ Pure Steam condensate sample in a 50 ml dry and clean beaker & measure the pH of the solution, at $25 \pm 2^\circ\text{C}$ on calibrated pH meter.

Acceptance Criteria:

Water for Injections/ Pure Steam condensate – Limit: 5.00 to 7.00.

6.3 CONDUCTIVITY: Take about 50 ml of Water for injections/ Pure steam condensate sample in a 100 ml dry and cleaned beaker and measure the conductivity of the sample, at $25 \pm 2^\circ\text{C}$ on calibrated conductivity meter.

Acceptance Criteria:

For - NMT 2.1 $\mu\text{S}/\text{cm}$.



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6.4 ACIDITY OR ALKALINITY:

Take 10 ml, freshly cooled sample in a borosilicate glass test tube, add 0.05 ml of methyl red solution, the resulting solution is not red.

Take 10 ml freshly cooled sample add 0.1 ml of bromothymol blue solution, the resulting solution is not blue.

6.5 NITRATES:

Take 5 ml water for injections/ pure steam condensate sample in a test tube immersed in ice add 0.4 ml of a 10 % w/v solution of potassium chloride and add 0.1 ml of Diphenylamine solution, dropwise with shaking add 5 ml of nitrogen free sulphuric acid. Transfer the tubes to a water bath at 50°C and allow standing for 15 minutes. Any blue colour in the solution is not more intense than that in a solution prepared at the same time and in the same manner. Using a mixture of 4.5 ml of nitrate free water and 0.5 ml of nitrates standard solution (2 ppm NO_3) (Test sample colour not dark blue comparison to nitrate standard solution).

6.6 TOTAL ORGANIC CARBON:

List Attached for routine testing of Total organic carbon for water for injections/ pure steam condensate

As per SOP.

Acceptance Criteria: NMT 0.5 mg per litre or 500 ppb.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Chemical Analysis Record for Water for Injections and Pure Steam condensate	
Annexure-II	Water for Injections/ Pure steam condensate sample Total organic carbon test list	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

In-House
USP-34, NF29



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MICROBIOLOGY DEPARTMENT

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE-I

CHEMICAL ANALYSIS RECORD FOR WATER FOR INJECTIONS AND PURE STEAM CONDENSATE

Sampling Point Details		A.R. No.	
Sample Name		Date of Receipt	
Sampling Point		Sampled On	
Sampled By		Sample Qty.	

S.No.	Test	Observation	Specification
1.	Description		Clear Colourless Liquid, Odourless
2.	pH		Limit: 5.0 to 7.0
3.	Acidity and Alkalinity		The resulting solution is not colored
5.	Nitrates		NMT 0.2 PPM
6.	Total Organic Carbon		NMT 0.5 mg per litre or 500 ppb
7.	Conductivity		NMT 2.1 μ S/cm

Remark: On the basis of above observation the sample complies / does not comply the entire test mentioned above as per IH Specification.

	Analysed By	Checked By	Approved By
Signature			
Date			



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ANNEXURE-II

WATER FOR INJECTIONS/ PURE STEAM CONDENSATE SAMPLE LIST FOR TOTAL ORGANIC CARBON TEST

LOCATION	SAMPLE POINT No.
WFI Plant Room	
WFI Plant Room	
WFI Plant Room	
DPI	
DPI	
DPI	
DPI	
T.P Line	
T.P Line	
T.P Line	
T.P Line	

Total organic carbon shall be performing for above mentioned Water for Injections and Pure steam condensate sampling point.