



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Quality Monitoring of Pure Steam

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 5

1.0 OBJECTIVE

To lay down procedure for Quality monitoring of pure steam.

2.0 SCOPE

This SOP is applicable for monitoring of pure steam in microbiology laboratory.

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Testing Parameter

4.1.1 Quality monitoring of Pure steam condensate includes testing of pure steam condensate for the below mentioned parameters -

4.1.1.1 Description

4.1.1.2 pH

4.1.1.3 Conductivity

4.1.1.4 TOC (Total Organic Carbon)

4.1.1.5 Bacterial Endotoxin Test

4.1.1.6 Microbiological Analysis

4.1.1.7 Non condensable gases

4.2 Parameter from 4.1.1 to 4.1.6 are to be tested as per standard test procedure of water for injection, and should meet the WFI Specifications.

4.3 Testing procedure of Non condensable gases

4.3.1 Apparatus: The apparatus is shown and described in Figure No.1.

4.3.2 Assembling of the test apparatus -

4.3.2.1 Connect the needle valve (f) to the steam service pipe as shown in Figure No.1.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Quality Monitoring of Pure Steam

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	2 of 5

4.3.2.2 Assemble the apparatus so that condensate will drain freely from the long rubber (i) tube into the glass-sampling pipe (e) with 'U' type end as shown in Figure No. - I.

4.3.2.3 Fill the container (d) with cold water until it overflows.

4.3.2.4 Fill the burette (a) and funnel (b) with cold water.

4.3.2.5 Invert them and place them in the container (d).

4.3.2.6 Draw out any air that has collected in the burette.

4.3.2.7 While keeping the steam sampling pipe (e) out of the container, open the needle valve and allow steam to purge the air from the pipe.

4.3.2.8 Place the pipe in the container, locate the end within the funnel, and add more cold water until it flows through the overflow pipe (k).

4.3.2.9 Place the empty measuring cylinder (g) under the container overflow.

4.3.2.10 Adjust the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of "Steam Hammer" to be heard.

4.3.2.11 Ensure that all the steam is discharged into the funnel and does not bubble out into the container.

4.3.2.12 Note the setting of the needle valve.

4.3.2.13 Close the valve.

4.3.2.14 Place a thermometer (j) to dip the tip in the water of container.

4.3.2.15 Ensure that the container is topped up with cold water and that the measuring cylinder is empty.

4.3.2.16 Draw out any air present in the burette. Note the Burette reading.

4.3.3 Testing -

4.3.3.1 Ensure that the sterilizer chamber is empty except for the usual chamber furniture.

4.3.3.2 Select and start the operating cycle.

4.3.3.3 When the steam supply to the chamber first opens, open the needle valve (f) to the previously noted setting.

4.3.3.4 Allowing a continuous sample of steam into the funnel sufficient to cause a small amount of steam hammer to be heard.

4.3.3.5 Allow the steam sample to condense in the funnel.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Quality Monitoring of Pure Steam

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	3 of 5

4.3.3.6 Any non-condensable gases will rise to the top of the burette.

4.3.3.7 Overspill formed by the condensate and the water displaced by the gases will collect in the measuring cylinder.

4.3.3.8 When the temperature of the water in the container reaches 70-75°C close the needle valve.

4.3.3.9 Note the reading of the Burette.

4.3.3.10 Note the volume of gas collected in the burette (V_b) as difference between initial and final reading and the volume of water collected in the measuring cylinder (V_c).

4.3.3.11 Calculate the fraction of non-condensable gases as a percentage as follows.

4.3.3.12 Fraction of non-condensable gases = $100 \times (V_b / V_c)$.

4.3.3.13 Carry out the three tests in three different days.

4.4 Acceptance Criteria

4.4.1 The test should be considered satisfactory if the fraction of non - condensable gases does not exceed 3.5 %.

4.4.2 The test should be done two more times to check consistency.

4.4.3 If the results of the three tests differ significantly, then the cause should be investigated before proceeding further.

5.0 SAFETY & PRECAUTIONS

Use thermal resistant gloves for sampling of water for injection and pure steam.

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

7.0 REFERENCES

Not applicable.

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

% : Percentage



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Quality Monitoring of Pure Steam

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 5

No. : Number

°C : Degree Centigrade

9.0 ANNEXURES

Annexure - I : Figure showing the apparatus

