



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Monitoring of Pure Steam

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 **OBJECTIVE:**

To lay down a procedure for monitoring of pure steam.

2.0 **RESPONSIBILITY:**

Microbiologist / Executive

3.0 **ACCOUNTABILITY:**

Head - Quality Assurance

4.0 **PROCEDURE:**

4.1 Prepare a 500 ml container by tightly covering its mouth with aluminum foil and depyrogenate it at 250°C for at least one hour.

4.2 Before collecting the sample put nose mask sterile hand gloves and disinfect hands and sampling point with 70% IPA and allow to dry.

4.3 Carry the depyrogenated container to the sampling point and collect at least 200 ml of condensed steam and label it.

4.4 After sampling cover the opening of the container tightly with aluminum foil.

4.5 Bring it to the microbiology laboratory and proceed for testing.

4.6 Pour 200 ml of the sample in sterile filtration cup with 0.22 micron membrane filter placed on a collecting and connected with rubber tubing.

4.7 After filtering the sample place the membrane filter on sterile agar plate and incubate the plate at 20-25 ° for 72 hrs followed by 30-35° for 5 day incubation.

4.8 Carry out LAL test as per and record the results in the format as mentioned in Annexure I.

4.9 Record the observations on the format as mentioned in Annexure-I.

5.0 **Points to be monitored :**

1. At Pure Steam Generator : PSG-1
2. Condensate from Autoclave : PSG-02

6.0 **Frequency of monitoring:** Once in a month for both the sampling points.

7.0 **Acceptance criteria :**

1. Bioburden: Should not be more than 10 CFU / 200 ml.
2. Bacterial Endotoxins: Not more than 0.125 IU / ml.

8.0 **ABBREVIATIONS:**

SOP = Standard Operating Procedure

9.0 **REFERENCES / ANNEXURES**

MCA ORANGE GUIDELINE 1997 / Annexure I attached.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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ANNEXURE I

MONITORING OF PURE STEAM

Sampling Point: _____ Medium used- SCD Agar : Incubation condition : 20-25 ° for 72 hrs followed by 30-35° for 5 day .

Date	Sampled By	Description*	Observation				Endotoxin (BET)	Inference	Tested by	Checked by
			-ve	+ve	Bacteria	Fungi				

- Limits:**
- Description :** Condensate of steam is clear, colorless and odorless liquid.;
 - Bacteria :** 10 Cfu / 200ml.;
 - Fungi :** Nil;
 - BET :** NMT 0.125 IU/ ml.

Frequency : Once in a month for both the sampling points.