



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Microbial Monitoring of Laminar Flow Clean Air Work Stations by Settle Plate

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 Objective

To lay down a procedure for Microbial Monitoring of Laminar Flow Clean Air Work Stations by Settle Plate in Microbiology laboratory.

2.0 Scope

This standard operating procedure is applicable for formulation plant of

3.0 Responsibility

Officer / Executive-Microbiology : Shall be responsible for Microbial Monitoring of Laminar Flow Clean Air Work Stations as per schedule.

Head-QC/ Designee : Shall be responsible for the compliance of this SOP

4.0 Abbreviations and Definitions

SOP : Standard Operating Procedure

QC : Quality Control

LAF : Laminar Air Flow

CFU : Colony Forming Unit

5.0 Procedure

- 5.1 Prepare Soyabean Casein Digest Agar plates as per SOP "Preparation and Use of Microbial Media".
- 5.2 Preincubate the plates at $32.5 \pm 2.5^{\circ}\text{C}$ for 24 hours prior to use for exposure in Laminar Air Flow.
- 5.3 Operate the LAF as per SOP "Operating Procedure for Vertical Laminar Down Flow Clean Work Station" and "Operating Procedure for Horizontal Laminar Flow Clean Work Station".
- 5.4 Expose the plates for half an hour on all three locations as shown in Annexure-1



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- 5.5 After completion of exposure cover and invert the plates and incubate at $22.5 \pm 2.5^{\circ}\text{C}$ for 72 hours followed by incubation at $32.5 \pm 2.5^{\circ}\text{C}$ for 48 hours.
- 5.6 After completion of incubation count the colony forming units and record cfu/plate in the format, Microbial Monitoring of Laminar Air Flow as per Annexure-2.
- 5.7 The acceptance criteria for plate count in LAF is less than 1 cfu/ plate/30 minutes.
- 5.8 Frequency for monitoring: Daily.

6.0 Forms and Records

- 6.1 Diagram for Locations in LAF for Monitoring : Annexure-1
- 6.2 Microbial Monitoring of Laminar Air Flow : Annexure-2

7.0 Reference

- 7.1 SOP: "Preparation and Use of Microbial Media".
- 7.2 SOP: "Operating Procedure for Vertical Laminar Down Flow Clean Work Station"
- 7.3 SOP: "Operating Procedure for Horizontal Laminar Flow Clean Work Station"

8.0 Distribution

- 8.1 Master Copy : Documentation Cell (Quality Assurance)
- 8.2 Controlled Copies : Quality Control, Quality Control

9.0 History

Date	Revision Number	Reason for Revision
	00	New SOP