



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Operating Procedure For Horizontal Laminar Flow Clean Air Work Station.	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 Objective

To lay down a procedure for the operation of Horizontal Laminar Flow Clean Air Work Station.

### 2.0 Scope

This Standard Operating Procedure is applicable for formulation plant.

### 3.0 Responsibility

Executive/Officer-Microbiology : Shall be responsible to follow the Operating procedure of Horizontal Laminar Flow Clean Air Work Station.

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

### 4.0 Abbreviations and Definitions

QC	:	Quality Control
SOP	:	Standard Operating Procedure
LAF	:	Laminar Air Flow
IPA	:	Isopropyl Alcohol
LPG	:	Liquefied Petroleum Gas
SS	:	Stainless Steel
UV	:	Ultra Violet
HEPA	:	High Efficiency Particulate Air
WG	:	Water Gauge

### 5.0 Procedure

5.1 Enter the aseptic area as per SOP titled "Entry and Exit Procedure in Microbiology Laboratory".

5.2 Connect the power chord of the Horizontal Laminar Air Flow Station with the mains and switch "ON" the mains of the aseptic area.



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- 5.3 Switch "ON" the blower and UV light with the help of switches present on the control panel of the equipment. The blower along with the UV light shall be kept 'ON' for half an hour before starting any operation under the Laminar Air Flow Station.
- 5.4 Check the air pressure of the Laminar Air Flow with the help of magnehelic gauges present on the control panel of the equipment. The pressure gauge reading shall be within 07 - 15 mm of WG, pressure shall be recorded in Annexure-1.
- 5.5 After half an hour, switch "OFF" the UV light from the control panel and switch "ON" the florescent tube light with the help of switches present on the control panel of the Laminar Air Flow Station. Blower shall be kept "ON" during work under LAF.
- 5.6 Connect the gas burner with the LPG cylinder with the help of non collapsible LPG pipe passing through the SS stopcock fitted on the right hand side of the Laminar Air Flow Station. Clean the LAF working bench and adjoining glass panels by spraying IPA (70%) filtered through 0.45  $\mu$  filter and allow it to dry.
- 5.7 Open the stop cock of the LPG gas cylinder and ignite the gas burner. Control the burner flame intensity with the help of SS gas stop cock fitted on the LAF bench.
- 5.8 Start the testing operations under the LAF unit by sitting in straight position in front of the LAF working Bench.
- 5.9 During Operations it shall be noted that the hands or the elbow should not touch the bench platform.
- 5.10 After completion of the testing operations, the Laminar Air Flow bench shall be cleaned thoroughly with IPA (70%) filtered through 0.45  $\mu$  filter and allow it to dry.
- 5.11 Switch "OFF" the Florescent tube lights, blowers with the help of switches fitted on the control panel and ensure that the magnehelic gauge reading should indicate '0'.
- 5.12 Spraying of (IPA 70%) or any solution shall not be done directly on the HEPA filter fitted in the LAF working station.
- 5.3 Record the cleanliness of LAF and duration of UV Light used in LAF Log Book as per Annexure-1.

### 6.0 Forms and Records

- 6.1 Horizontal LAF Log Book : Annexure-1



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### 7.0 Distribution

- 7.1 Master Copy : Documentation cell (Quality Assurance)
- 7.2 Controlled Copies : Quality Control, Quality Assurance

### 8.0 History

Date	Revision Number	Reason for Revision