



# PHARMA DEVILS

WAREHOUSE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Warehouse	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Reverse Laminar Air Flow Unit	<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 Operation and Cleaning of Reverse Laminar Air Flow Unit (RLAF).

### 2.0 SCOPE:

This SOP is applicable to Operation and Cleaning of RLAF Unit during sampling and dispensing activity in Warehouse.

### 3.0 RESPONSIBILITY:

Executive/Officer-QC

Executive/Officer Warehouse

### 4.0 ACCOUNTABILITY:

Head Warehouse

### 5.0 ABBREVIATIONS:

IPA	Iso Propyl Alcohol
Ltd	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
RLAF	Reverse Laminar Air Flow
SOP	Standard Operating Procedure
WH	Warehouse

### 6.0 PROCEDURE:

#### 6.1 Operation Of RLAF Unit:

- 6.1.1 Warehouse/QC personnel shall check and ensure the ZERO reading in all three magnehelic gauges of RLAF unit when the RLAF unit is switched off.
- 6.1.2 Warehouse/QC personnel shall ensure that the area and RLAF Unit is cleaned.
- 6.1.3 Warehouse/QC personnel shall check the calibration due date of Magnehelic gauges.
- 6.1.4 Switch "ON" the blower.
- 6.1.5 Switch "ON" the light.
- 6.1.6 Allow the RLAF to run for at least 15 minutes before the start of observation and recording.
- 6.1.7 Warehouse / QC personnel shall ensure pressure differential limit of pre-filter **between 7-25 mm** of pascal.
- 6.1.8 Warehouse / QC personnel shall ensure pressure differential limit of fine filter **between 4-8 mm** of water.



# PHARMA DEVILS

WAREHOUSE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Warehouse	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Reverse Laminar Air Flow Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**6.1.9** Warehouse / QC personnel shall ensure pressure differential limit of HEPA-filter **between 5-15 mm** of water.

**Remark:** For Large Volume Parenteral Block RLAF pressure differential limit of pre-filter is between 2-6 mm of water. (Pressure Differential Record of RLAF shall be record as per **Annexure III**).

**6.1.10** In case reading is out of limit, stop the operation and intimate Head warehouse and maintenance for rectification.

**6.1.11** Warehouse personnel shall enter the RLAF operation details as per **of SOP**.

**6.1.12** Pressure Differential Record of RLAF shall be record as per **Annexure I**.

**6.1.13** After completion of the sampling and dispensing activity blower & light of RLAF shall be continues in running condition.

### **6.2 Cleaning of RLAF Unit:**

**6.2.1** RLAF shall be Switch "ON" while sampling & dispensing activity is continue for Dry mopping & Wet mopping cleaning in RLAF booth ,If sampling /dispensing planning is going continues.

**6.2.2** RLAF shall be Switch "OFF" if further sampling/dispensing activity is not plan in particular booth.

**6.2.3** RLAF shall be Switch "OFF" in every 24 hours for RLAF filter cleaning or replace, if sampling & dispensing activity going continue.

**6.2.4** Clean the internal floor surface of the RLAF with use vacuum cleaner in every 24 hours if open RLAF filter for cleaning or replacement. Vacuum cleaner shall use if required to shocking dust from inside surface of RLAF.

**6.2.5** Ensure that surface of RLAF is visually clean before start sampling/dispensing activity.

**6.2.6** Store/QC personnel shall inform to engineering by request intimation for Cleaning filter or replacement filter of RLAF of sampling and dispensing booth in every 24 hours.

**6.2.7** RLAF filters cleaning or replacement by engineering department in every day in 24 hours. Record for "Filter Replacement" should be in Annexure-II RLAF Utilization Log Book of SOP.

**6.2.8** RLAF unit shall be mopped with 70% IPA once in a day before starting the activity and enter the details in remarks column of RLAF Utilization Log Book of SOP.

**6.2.9** Filter cleaning activity of RLAF & LAF filters shall be carried out as per SOP.

**6.2.10** For RLAF & LAF filters cleaning, intimation shall be provided to engineering department as per Annexure-III.



# PHARMA DEVILS

WAREHOUSE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Warehouse	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Reverse Laminar Air Flow Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**6.2.11** As per intimation, concern personnel of engineering department shall perform the assigned job i.e. filter cleaning/ replacement and same shall be recorded in intimation slip.

**6.2.12** After completion of replacement/ cleaning activity of filters, dully filled intimation shall be kept by engineering department and second copy shall be kept at user department.

*Note: For Ointment/Injection Block intimation for filter Cleaning/Replacement shall be sent to engineering after completion dispensing of product.*

*Filter Cleaning/replacement record shall be recorded in the remarks column of RLAF Utilization record as "Filter replacement" for injection block & "Filter replacement /WI" for Ointment block.*

### 7.0 ANNEXURES:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	Pressure Differential Record of RLAF	
Annexure- II	Pressure Differential Record of RLAF for Large Volume Parenteral Block	
Annexure- III	Intimation for RLAF/LAF filter cleaning/ replacement	

**ENCLOSURE:** SOP Training Record

### 8.0 DISTRIBUTION:

- Controlled copy No.01                      Quality Assurance
- Controlled copy No.02                      Warehouse
- Master copy                                      Quality Assurance

### 9.0 REFERENCES:

Operation Manual

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

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





