



# PHARMA DEVILS

## ENGINEERING DEPARTMENT

### STANDARD OPERATING PROCEDURE

<b>Department:</b> Engineering	<b>SOP No.:</b>
<b>Title:</b> Cleaning of LAF/RLAF Filter	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

#### 1.0 REVISION HISTORY

Rev. No.	Details of changes	Reason for change
00	NIL	NEW SOP

#### 2.0 OBJECTIVE

The Objective of this SOP is to describe the procedure for cleaning of filters being used in Laminar Air Flow (LAF) unit and Reverse Laminar Air Flow (RLAF) Unit. To ensure Proper Maintenance of filters. To provide recommendation for Replacement of filters, if required.

#### 3.0 SCOPE

This SOP is to describe the procedure for cleaning of filters being used in Laminar Air Flow (LAF) unit and Reverse Laminar Air Flow (RLAF) unit.

#### 4.0 RESPONSIBILITY

**4.1** The Operator shall be:

**4.1.1** Responsible for cleaning of LAF /RLAF Filters.

**4.1.2** Responsible to maintain the cleaning record.

**4.2** The Engineer shall be:

**4.2.1** Responsible for assurance of proper cleaning.

**4.2.2** Corrective action for any deviation.

#### 5.0 ACCOUNTABILITY

Head –Engineering Services



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#### 6.0 PROCEDURE:

- 6.1 Switch 'Off' the Unit, of which filters to be cleaned.
- 6.2 A person carrying out the filter cleaning activity should wear following apparel.
  - 6.2.1 Clean boiler suit.
  - 6.2.2 Nose mask.
  - 6.2.3 Rubber hand gloves.
- 6.3 Open the inspection door of filter section, if applicable.
- 6.4 Remove the filter and put it into the polythene bag.
- 6.5 Close the inspection door of filter section with polythene bag.
- 6.6 Take the filters to 'Filter Washing' area.
- 6.7 Remove the filter from polythene bag and put it in the reverse direction to normal flow.
- 6.8 Open the compressed air valve and clean the filter with filtered compressed air.
- 6.9 Close the compressed air valve.
- 6.10 Open the potable water valve and clean the filter with filtered potable water.
- 6.11 Close the 'potable water' valve.
- 6.12 Put the filter in the direction of normal flow.
- 6.13 Clean the filter as per points 5.8 to 5.11.
- 6.14 Ensure that filter is completely dried. Blow the compressed air, if required to dry the filter.
- 6.15 Remove the filter and check visually for its integrity and any damage of gasket. Rectify it, if required.
- 6.16 Put the filter into fresh polythene bag.
- 6.17 Open the inspection door and wipe the filter section and blower using dry and clean duster.
- 6.18 Fix back the filter in the filter section.
- 6.19 Close the inspection door and ensure no leakage.
- 6.20 Maintain the record of filter cleaning. (Annexure - I).
- 6.21 FREQUENCY:
  - 6.21.1 Dispensing Area Active /Inactive –Weekly & Sampling Area Active /Inactive-Fifteen days.
  - 6.21.2 Cephalosporin Block/ General Block Injection - Fifteen days.



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#### 7.0 Annexure

Annexure-I : Laminar Air Flow Filter Cleaning Record Cephalosporin Block

Annexure-II : Laminar Air Flow Filter Cleaning Record General Block Injection

Annexure-III : Reverse Laminar Air Flow Filter Cleaning Record Ware-house

#### 8.0 References (S)

NIL

#### 9.0 Glossary

SOP : Standard Operating procedure

No : Number

LAF : Laminar Air Flow



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#### ANNEXURE-I

DATE: \_\_\_\_\_

AREA: \_\_\_\_\_

S. No.	LAF CODE	LOCATION	FILTER CLEANING DONE/ NOT DONE	DONE BY
01		VIAL WASHING AND STERILIZATION AREA		
02		UNIT PREPRATION		
03		GARMENT WASHING		
04		OVER TURN TABLE STERILE AREA		
05		VIAL FILLING STERILE AREA		
06		BUNGING SEALING STERILE AREA		
07		OVER TURN TABLE STERILE AREA		
08		SEALING STERILE AREA		
09		COOL ZONE STERILE AREA		
10		COOL ZONE STERILE AREA		
11		BLENDING STERILE AREA		
12		MOBILE		
13		GARMENT CUBICAL CHANGE ROOM-02		
14		GARMENT CUBICAL CHANGE ROOM-03		
15		PAS BOX AT IRM		
16		PASS BOX AT WASHING AREA		

**FREQUENCY:** ALL PRE-FILTERS OF LAMINAR AIR FLOW TO BE CLEANED ONCE IN FIFTEEN DAYS.

**CAUTION:** BEFORE CARRYING OUT PRE FILTER CLEANING, SWITCH 'OFF' THE LAF/RLAF AND DISPLAY THE 'UNDER MAINTENANCE' BOARD.

<b>CHECKED BY</b>	<b>NEXT CLEANING DUE:</b>



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#### ANNEXURE-II

DATE: \_\_\_\_\_

AREA: \_\_\_\_\_

S. No.	LAF CODE	LOCATION	FILTER CLEANING DONE/ NOT DONE	DONE BY
17		VIAL WASHING AND STERILIZATION AREA		
18		UNIT PREPRATION		
19		GARMENT WASHING		
20		OVER TURN TABLE STERILE AREA		
21		VIAL FILLING STERILE AREA		
22		BUNGING SEALING STERILE AREA		
23		OVER TURN TABLE STERILE AREA		
24		SEALING STERILE AREA		
25		COOL ZONE STERILE AREA		
26		COOL ZONE STERILE AREA		
27		BLENDING STERILE AREA		
28		MOBILE		
29		GARMENT CUBICAL CHANGE ROOM-02		
30		GARMENT CUBICAL CHANGE ROOM-03		
31		PAS BOX AT IRM		
32		PASS BOX AT WASHING AREA		

**FREQUENCY:** ALL PRE-FILTERS OF LAMINAR AIR FLOW TO BE CLEANED ONCE IN FIFTEEN DAYS.

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#### ANNEXURE-III

DATE: \_\_\_\_\_

AREA: \_\_\_\_\_

S. NO.	LAF CODE	LOCATION	FILTER CLEANING DONE/ NOT DONE	DONE BY
01		LAF VIAL WASHING (DPI)		
02		LAF AMPOULE WASHING		
03		LAF VIAL WASHING (LIQUID)		
04		LAF UNIT PREPARATION (DPI)		
05		LAF GARMENT WASHING-1		
06		LAF GARMENT WASHING-2		
07		LAF UNIT PREPARATION (LIQUID)-1		
08		LAF UNIT PREPARATION (LIQUID)-2		
09		LAF FILLING AND BUNGING MACHINE (DPI)-1		
10		LAF FILLING AND BUNGING MACHINE (DPI)-2		
11		LAF SEALING MACHINE (DPI)		
12		LAF BLENDING		
13		LAF LYOPHILIZER-1		
14		LAF GARMENT CUBICLE ASEPTIC-2		
15		LAF GARMENT CUBICLE ASEPTIC-2		
16		LAF GARMENT CUBICLE ASEPTIC-3		
17		LAF GARMENT CUBICLE ASEPTIC- MFG		

**FREQUENCY:** ALL PRE-FILTERS OF LAMINAR AIR FLOW TO BE CLEANED ONCE IN FIFTEEN DAYS.

**CAUTION:** BEFORE CARRYING OUT PRE FILTER CLEANING, SWITCH 'OFF' THE LAF/RLAF AND DISPLAY THE 'UNDER MAINTENANCE' BOARD.

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AREA: \_\_\_\_\_

S. No.	LAF CODE	LOCATION	FILTER CLEANING DONE/ NOT DONE	DONE BY
01		LAF LYOPHILIZER-2		
02		LAF AUTOCLAVE COOLZONE-1		
03		LAF AUTOCLAVE COOLZONE-2		
04		LAF DHS COOL ZONE		
05		LAF BUNGPROCESSOR COOL ZONE		
06		LAF STERILE EQUIPMENT STORAGE (COOL ZONE)		
07		LAF FILTRATION-1		
08		LAF FILTRATION-2		
09		LAF AMPOULE FILLING AND SEALING-1		
10		LAF AMPOULE FILLING AND SEALING-2		
11		LAF FILLING AND BUNGING MACHINE ( LIQUID)-1		
12		LAF FILLING AND BUNGING MACHINE (LIQUID)-2		
13		LAF SEALING MACHINE ( LIQUID )		
14		DYNAMIC PASS BOX		
15		DYNAMIC PASS BOX		
16		DYNAMIC PASS BOX		
17		DYNAMIC PASS BOX		

**FREQUENCY:** ALL PRE-FILTERS OF LAMINAR AIR FLOW TO BE CLEANED ONCE IN FIFTEEN DAYS.

**CAUTION:** BEFORE CARRYING OUT PRE FILTER CLEANING, SWITCH 'OFF' THE LAF/RLAF AND DISPLAY THE 'UNDER MAINTENANCE' BOARD.

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DATE: \_\_\_\_\_

AREA: \_\_\_\_\_



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S.NO.	RLAF CODE	LOCATION	PRE-FILTER CLEANING DONE/ NOT DONE	MAICROVEE- FILTER CLEANING DONE/ NOT DONE	DONE BY
01		DISPENSING AREA ACTIVE			
02		DISPENSING AREA INACTIVE			
03		SAMPLING AREA ACTIVE			
04		SAMPLING AREA INACTIVE			

**FREQUENCY:** DISPENSING AREA ACTIVE /INACTIVE –WEEKLY & SAMPLING AREA ACTIVE /INACTIVE-FIFTEEN DAYS.

**CAUTION:** BEFORE CARRYING OUT PRE FILTER CLEANING, SWITCH 'OFF' THE LAF/RLAF AND DISPLAY THE 'UNDER MAINTENANCE' BOARD.

CHECKED BY	NEXT CLEANING DUE: