



STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Vertical Laminar Air Flow Unit and Mobile LAF

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Vertical Laminar Air Flow Unit and mobile LAF.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Vertical Laminar Air Flow Unit and mobile LAF in Production Area.

3.0 RESPONSIBILITY:

Officer / Executive Production: Preparation, training and effective implementation of this SOP.

Officer / Executive Engineering: For cleaning of Pre filter and effective implementation of SOP.

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

ΔP	Differential Pressure
HEPA	High Efficiency Particulate Air
ID No.	Identification Number
IPA	Iso Propyl Alcohol
LAF	Laminar Air Flow
Ltd.	Limited
mm	Millimeter
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Switch "ON" the lights and blower of LAF 30 minutes before start of any activity inside the LAF.

6.1.2 Check the reading of differential pressure across the pre filter showing on Magnehelic gauge and ensure that it should be maintained in between range of 02-08 mm of water, if available in the respective LAF.

6.1.3 Check the reading of differential pressure across the HEPA filter showing on Magnehelic gauge and ensure that it should be maintained in between range of 10-15 mm of water.

6.1.4 For Oral liquid LAF facility, Check the reading of differential pressure in between Pre filter and HEPA showing on Magnehelic gauge and ensure that it should be maintained in between range of 05-15 mm of water.

6.1.5 If any abnormal sound is observed from the LAF Unit, the LAF Unit must be checked for its wear and tear.



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- 6.1.6 After completion of work, switch “OFF” the Light & Blower.
- 6.1.7 Check the pressure drop across the unit periodically.
- 6.1.8 Check the physical condition of Pre filters when reading on Magnehelic gauge is not showing in between 02-08 mm of water, if available.
- 6.1.9 Check the integrity of HEPA filters when reading on Magnehelic gauge if not showing in between 10-15 mm of water in injectable facility.
- 6.1.10 Check the integrity of HEPA filters when reading on Magnehelic gauge is not showing in between 5-15 mm of water for oral liquid LAF facility
- 6.1.11 If any HEPA filter is damaged replace it with new HEPA filter.
- 6.1.12 Check the start indication light etc. frequently if required.
- 6.1.13 Before and after operation, Record the Differential Pressure details in **Annexure-II**, Titled “**LAF Differential Pressure Record**” and for oral liquid record the cleaning detail in **Annexure-III** Titled “**LAF Grill & Pre-Filter Cleaning Record (Oral Liquid)**”.

6.2 CLEANING AND REPLACEMENT OF PRE FILTERS:

- 6.2.1 Switch ‘Off’ the respective vertical LAF unit and mobile LAF.
- 6.2.2 Take gentle moping with 70% v/v filtered IPA solution on the Outer C.G Screen covering of HEPA provided in Oral liquid as for B type cleaning.
- 6.2.3 Take out the pre-filters of vertical LAF/mobile LAF, place in a polybag and Label it with **to be cleaned** status label and transfer it to designated filter washing area.
- 6.2.4 Send the Intimation for cleaning of filter as per **Annexure**.
- 6.2.5 Clean these pre filters as per **SOP**. Cleaning record of pre filters shall be maintained as per **Annexure**.
- 6.2.6 The existing prefilters shall be replaced with additional cleaned pre filter.
- 6.2.7 Sanitize the cleaned pre filters with filtered 70% v/v IPA solution and then transfer into respective area.
- 6.2.8 Sanitize the SS frame of Pre –Filters and SS grill of respective LAF.
- 6.2.9 Fix the pre filter along with frame into designated place in the LAF.
- 6.2.10 Whole unit of LAF should be cleaned / mopped with 70% v/v filtered IPA solution.
- 6.2.11 Spray 70% v/v filtered IPA solution all over the filters and cover frame.
- 6.2.12 Record the Cleaning details in **Annexure-I**, Titled as “**LAF Cleaning Record**”
- 6.2.13 **Frequency of cleaning of Mobile LAF:** Daily or whenever required.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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6.2.14 Frequency of cleaning of pre filters of vertical LAF and mobile LAF

6.2.14.1 In Dry Powder Injection line: During product change over and weekly \pm 2 days in case of No production activity.

6.2.14.2 In Liquid Injection and Ophthalmic line: Weekly \pm 2 days.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	LAF Cleaning Record	
Annexure-II	LAF Differential Pressure Record	
Annexure-III	Vertical LAF HEPA And Pre Filter Differential Pressure Record (Oral Liquid)	
Annexure-IV	Mobile LAF Cleaning Record	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCE:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

