	Title : Operation, Cleaning and Maintenance of Laminar Air Flow Unit	SOP NUMBER :	SOP/PMH/013-00
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1.0 OBJECTIVE

To lay down the procedure for operation, cleaning and maintenance of laminar air flow unit.

2.0 SCOPE

This SOP is applicable for operation, cleaning and maintenance of laminar air flow unit in Microbiology laboratory of Pharma Micro Hub Pvt Ltd.

3.0 RESPONSIBILITY

3.1 All personnel who are operating the laminar air flow unit in microbiology laboratory are responsible for adherence to this procedure.

4.0 ACCOUNTABILITY

4.1 Head–Microbiology / his designee is accountable for overall compliance of this SOP.

5.0 PROCEDURE

5.1 Precautions:

5.1.1 Do not perform rigorous movements inside the LAF, which disrupt the air flow patterns.

5.1.2 Ensure the equipments placed inside the LAF do not disturb the air flow.

5.1.3 Replace the UV lamp for every 7500 hrs.

5.1.4 Ensure the Laminar Air Flow Unit (LAF) is continuously kept in ‘ON’ condition in sterility testing area.

5.1.5 Ensure that the UV light shall be switched OFF before starting any microbial analysis.

5.1.6 Sanitize the gloved hands with 70% v/v sterile filtered IPA. In case of any spillages during the testing activity use sporicidal disinfectant for cleaning.

5.1.7 Small spillage during the testing within the LAF can be handled immediately by removing the spillage with sterile lint free cloth moistened with disinfectant.


5.2 Operating procedure:

5.2.1 Press the Blower on/off button at digital display and keep the blower present in the LAF is in ON condition before start of analysis.

5.2.2 Press the CFL LAMP on/off button present at digital display to keep the CFL lamp in ON condition before starting of analysis.

5.2.3 Clean the LAF work bench with diluted and filtered sporicidal disinfectant by using lint free cloth.

5.2.4 Press the UV LAMP on/off button at digital display and keep the UV lamp in ON condition approximately 30 minutes before starting the testing activity.

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- 5.2.5 After the completion of UV lamp exposure time, switch OFF the UV lamp by pressing UV LAMP on/off button again wait for 5 minutes before start of the analysis.
- 5.2.6 Record the UV lamp burning hours (ON time and OFF time and cumulative hours) in the Annexure -I.
- 5.2.7 Check the Differential Pressure of the LAF before starting of analysis and enter the reading details in Annexure-I.
- 5.2.8 Differential Pressure of LAF should be between 10 -25 mm of water column.
- 5.2.9 If pressure is beyond the limit immediately inform to head of the department and engineering department for necessary actions.
- 5.2.10 Enter the purpose of the activity and activity initiation timings details in Annexure-I
- 5.2.11 Required materials for analysis should be transferred in to the LAF unit before starting of the activity.
- 5.2.12 Materials and article should be sanitized with 70% v/v sterile filtered IPA before placing inside the LAF.
- 5.2.13 After completion of the activity clean the laminar air flow bench with lint free cloth moistened with Diluted and filtered Sporicidal disinfectant.
- 5.2.14 After completion of the activity observe the differential pressure of LAF and enter the reading and also enter the activity closing time details in Annexure-I.
- 5.2.15 Enter the LAF off details in Annexure-I
- 5.3 Cleaning procedure:**
- 5.3.1 Clean the laminar air flow work bench before start of the initial analysis and after completion of each analysis of particular day of testing.
- 5.3.2 Use sterile lint free cloth moistened with filtered Sporicidal disinfectant for cleaning of sterility testing LAF.
- 5.3.3 During cleaning the LAF work bench, clean the farthest end to nearest end and do not touch the filter.
- 5.3.4 Clean the external area of LAF unit daily once with sterile lint free cloth by using routine disinfectant which was prepared for microbiology area cleaning.
- 5.3.5 After completion of cleaning enter the cleaning details in Annexure-I.
- 5.4 Maintenance procedure:**
- 5.4.1 Preventive maintenance shall be performed as per the procedure defined in SOP.
- 5.4.2 Periodic qualification shall be performed as per the SOP

6.0 ABBREVIATIONS



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- 6.1 LAF : Laminar Air Flow
- 6.2 LBPC : Liquid Borne Particulate Count
- 6.3 UV : Ultra Violet
- 6.4 IPA : Iso propyl alcohol
- 6.5 WC : Water column
- 6.6 CFL : Compact Florescent Lamp
- 6.7 hrs : hours

7.0 ANNEXURES

- 7.1 Annexure-I: Operation, Cleaning and Maintenance record of Laminar Air Flow Unit.

8.0 REFERENCES

- 8.1 Preventive Maintenance of Equipment's.
- 8.2 Validation master plan

9.0 CHANGE HISTORY

- 9.1 New Sop

END OF DOCUMENT



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Equipment Name:

Equipment ID:

Date	Activity			UV Lamp Burning Hours			Details of the microbial analysis	Start of Activity		End of Activity		Done by	Reviewed By
	C	O	M	ON Time	OFF Time	Cumulative hours		Time	DP	DP	Time		

C=Cleaning, O=Operation, M=Maintenance. ✓ - Activity Done / X -Activity Not Done. Differential pressure limit (DP): (10-25mm of WC)