



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation, Calibration and Cleaning of RLAF	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for operation, Calibration and cleaning of R-LAF.

2.0 SCOPE:

This procedure is applicable to operation, Calibration and cleaning of R-LAF.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control, Engineering.

Head – Quality Control

4.0 PROCEDURE:

4.1 Operation of R-LAF:

4.1.1 Enter into sampling booth area as per SOP and check the air Pressure Differential and record as per Annexure-II of SOP.

4.1.2 Switch “ON” light of sampling area.

4.1.3 Check and ensure the cleanliness of R-LAF.

4.1.4 Press light key to switch on the tube light.

4.1.5 Press blower key to switch on the blower.

4.1.6 Leave it for at least 15 minutes before sampling to attain the required air Pressure Differential.

4.1.7 Ensure that the air pressure differential of HEPA filter magnehelic gauge is between 8 and 18 mm of water, Prefilter magnehelic gauge is between 2 and 4 mm of water and Micro-vee filter magnehelic gauge is between 2 and 4 mm of water.

4.1.8 Record the observation for HEPA filter magnehelic gauge, Prefilter magnehelic gauge and Micro-vee filter magnehelic gauge as per Annexure-I.

4.1.9 If the reading is beyond the limit, immediately inform to maintenance department for taking corrective action.

4.1.10 Start sampling of the materials followed by bringing one container at one time under the R-LAF of sampling area.

4.1.11 After completion of sampling, record the sampling activity as per Annexure-IV of SOP.



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4.2 Cleaning of R-LAF:

- 4.2.1 Clean the outer surface and working area of R-LAF with a lint free cloth moistened with filtered 70% v/v IPA.
- 4.2.2 Clean the working area of R-LAF before and after every operation. Clean the outer surface of R-LAF daily and records in Annexure-I.
- 4.2.3 If the next sampling is of the same raw material, clean the only R-LAF by dry mop and don't off the R-LAF.
- 4.2.4 While in case if the next sampling is of different raw material, Switch off the R-LAF and remove the sampling devices & material from the sampling area and clean and clean with dry lint free cloth followed by lint free cloth moistened with filtered 70% v/v IPA and follow the further cleaning procedure as per SOP.

4.3 Cleaning of R-LAF filter :

- 4.3.1 Cleaning of the R-LAF filter by Engineering personnel as per their respective SOP.

4.4 Calibration :

- 4.4.1 Calibration of magnehelic gauge is to be calibrated by authorized or trained engineering personnel.
- 4.4.2 If the reading are exceeding the acceptable limit put an "OUT OF CALIBRATION "tag and proceed as per SOP.
- 4.4.3 Calibrate frequency: Once in Year.

5.0 ANNEXURE (S):

Annexure – I: R-LAF activities log.

6.0 REFERENCE (S):

SOP Entry and Exit into Sampling Booth Area
SOP Operation and Cleaning of Sampling Area.

7.0 ABBREVIATION (S)/ DEFINITION (S):

IPA : Isopropyl Alcohol
R-LAF: Reverse Laminar Air Flow



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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SOP : Standard Operating Procedure

HEPA : High Efficiency Particulate Air

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	----



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ANNEXURE I
R-LAF ACTIVITIES LOG

Date	*Zero check	On time	Reading noted time	Pressure differential of R-LAF (mm of water)			Activity**	Material	A. R. No.	Operation		Done by	Checked by
				Across Micro-vee filter (2-4)	Across pre-filter (2-4)	Across HEPA filter limit (8-18)				Start at	End at		

*Zero check of R-LAF: Ok / Not Ok

**Sampling / Cleaning / Maintenance