



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Booth (Packing Material)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for operation and cleaning of sampling booth (Packing material).

2.0 SCOPE:

This procedure is applicable to operation and cleaning of sampling booth (Packing material).

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head - Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Operation of sampling booth:

5.1.1 Enter into sampling area through Air Lock.

5.1.2 Check and ensure the cleanliness of R-LAF and Sampling area.

5.1.3 Switch “ON” mains of the light of this area.

5.1.4 Switch “ON” mains of the R-LAF to start the system and lights.

5.1.5 Leave it for 15 minutes to attain the required air pressure differential.

5.1.6 Ensure that the air pressure differential of HEPA filter magnehelic gauge is between 5 - 15 mm and record the observation as per Annexure-I.

5.1.7 Monitor the temperature with the calibrated hygrometer of sampling area and record the observation as per Annexure-I.

5.1.8 Ensure that the temperature of the sampling booth area is below 25°C.

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

5.1.10 Start sampling of the materials under the sampling booth R-LAF area.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Booth (Packing Material)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.1.11 Record the sampling activity log as per Annexure-II.

5.1.12 After completion of activity, switch "OFF" the R-LAF.

5.2 Cleaning of sampling booth after sampling:

5.2.1 After completion of sampling, remove material from the R-LAF.

5.2.2 Remove the residue of material from the R-LAF area by vacuum cleaner.

5.2.3 Switch off the electric supply from the mains.

5.2.4 Clean the floor, wall, light fixture, surfaces & corners of R-LAF, pallets. table & weighing balance with wet mop.

5.2.5 Sanitize the sampling area with the help of 70% v/v IPA solution at the end of the work.

5.2.6 Record the cleaning activity in cleaning record of R-LAF as per Annexure-II.

5.2.7 Put the status label as per Annexure-III.

5.3 Cleaning of R-LAF filter:

Frequency: Weekly cleaning (By Engineering personnel)

5.3.1 Switch off the R-LAF from the mains supply (Before "switching off" ensure there is not material kept inside).

5.3.2 Dismantle the pre-filters from the R-LAF.

5.3.3 Put the filters in double polybag & close the bag.

5.3.4 Transfer the polybag along with the filters to the filter cleaning area.

5.3.5 Clean the filter as per SOP.

5.3.6 Affix the filters to its original place at R-LAF.

6.0 ABBREVIATION(S):

R-LAF : Reverse Laminar Air Flow

S.S : Stainless Steel

IPA : Iso Propyl Alcohol

SOP : Standard Operating Procedure

7.0 REFERENCE(S):

NA



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Booth (Packing Material)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

8.0 ANNEXURE(S):

Annexure-I : Temperature and Pressure differential record of sampling booth (Packing material)

Annexure-II : Sampling booth activities log

Annexure-III : Status label of sampling booth

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Booth (Packing Material)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE II

Sampling booth activities log					Identification. No:		
S.No.	Date	*Activity	A.R. No/ B.No.	Operation		Done By	Remark
				Started at	Completed at		

*Sampling/ Cleaning/ Maintenance



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Booth (Packing Material)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE III

Status Label of Sampling Booth

MATERIAL :

A.R.No. :

STATUS :

SIGN :

DATE :