



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for operation and cleaning of Sampling Area.

2.0 SCOPE:

This procedure is applicable to operation and cleaning of Sampling Area.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control
Head – Quality Control

4.0 PROCEDURE:

4.1 Operation of sampling booth:

- 4.1.1 Enter into sampling area as per SOP and check the air pressure differential record as per Annexure-II.
- 4.1.2 Check and ensure the cleanliness of R-LAF area and sampling area.
- 4.1.3 Switch “ON” mains of the light of sampling area.
- 4.1.4 Monitor the temperature and relative humidity with the calibrated hygrometer of sampling area before sampling and record the observation as per Annexure-I.
- 4.1.5 Ensure that the temperature of the sampling area is $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ (19°C - 25°C) and relative humidity $50\% \pm 5\%$ (For Sampling Area-I RH limit is $35\% \pm 5\%$)
- 4.1.6 If the reading is beyond the limit, immediately inform to maintenance department for taking corrective action.
- 4.1.7 Start sampling of the materials followed by bringing one container at one time under the R-LAF area of sampling area.
- 4.1.8 In case of sampling of raw material which require nitrogen flushing, each container shall be flushed with nitrogen gas using the Nitrogen user point before and after sampling when the inner bags are opened in order to have an inert atmosphere.
- 4.1.9 After completion of sampling, record the sampling activity as per Annexure-IV
- 4.1.10 For next sampling, follow the same procedure defines in 4.1 after cleaning of sampling



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

area.

4.1.11 Switch off the light of sampling booth at the end of the sampling for the day.

4.2 Cleaning of sampling area:

4.2.1 Frequency:

4.2.1.1 Daily or before the start of sampling and during sampling change over.

4.2.2 Daily Cleaning:

4.2.2.1 Wet mop the sampling area, floor, walls, ceiling, pallets, fitting along with SS table, Balances, SS trolley, Outside of the container keeping utensils with 1.0 % v/v Teepol Solution followed by purified water.

4.2.3 Cleaning of sampling area after sampling:

4.2.3.1 If the next sampling is of the same raw material, clean the only R-LAF area by dry mop.

4.2.3.2 While in case if the next sampling is of different raw material, clean the sampling area as per below procedure.

4.2.3.2.1 Remove the sampling devices & material from the sampling area.

4.2.3.2.2 Wrap the sampling devices in a polybag and affix the status label of "TO BE CLEANED" (SOP: QCD/041) and then transfer it to washing area through material air lock by the lab technician.

4.2.3.2.3 Clean the sampling area, material air lock area and personal air lock area.

4.2.3.2.4 Clean the floor, wall, light fixings, doors, surfaces, corners, pallets, table & weighing balance with wet mop.

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

4.2.3.3 Record the cleaning activity as per Annexure – IV.

4.2.3.4 Put the status label as per Annexure - III.

Precautions: Analyst has ensure the cleaning of sampling area Before starting the sampling activity.

5.0 ANNEXURE (S):

Annexure – I: Temperature and Humidity record of sampling area.

Annexure – II: Air pressure differential record.



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Cleaning of Sampling Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Annexure – III: Specimen for status label of sampling area.

Annexure – IV: Sampling booth area activities log.

6.0 REFERENCE (S):

SOP: Entry and Exit into Sampling Booth Area

SOP: Cleaning and Usage of Sampler and Sampling Devices and their Numbering System.

SOP: Preparation, approval, distribution, control, revision and Destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S)/ DEFINITION (S):

IPA : Isopropyl Alcohol

R-LAF: Reverse Laminar Air Flow

S.S : Stainless Steel

SOP : Standard Operating Procedure

HEPA : High Efficiency Particulate Air



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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Title: Operation and Cleaning of Sampling Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

REVISION CARD

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

