



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Checking of Airflow Pattern	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for checking of airflow pattern.

2.0 SCOPE:

This SOP is applicable to all air-handling units (AHU) and laminar air flow (LAF) units in.

3.0 RESPONSIBILITY:

Technician / Engineer.

Head Of Department - Engineering.

4.0 PROCEDURE:

4.1 Airflow pattern checking should be done at rest condition.

4.2 Inform Quality Assurance (QA) and concerned department about the plan.

4.3 Ensure that all the production activities are stopped and machines are put 'Off'.

4.4 Cover all the production equipment with poly bags.

4.5 Start the respective AHU / LAF for which the flow pattern is to be checked.

4.6 Person carrying out flow pattern checking activity should wear gowning as per respective area.

4.7 Air flow pattern shall be carried out by Titanium Tetra Chloride (TTCl₄) / Water Base Fogger.

4.8 Conducting the Air Flow pattern by Using TTCl₄ method.

4.8.1 Wrap a piece of cotton / lint free cloth at one end of a glass rod and other end shall be used for holding.

4.8.2 Dip the cotton / lint free cloth end of the glass rod in TTC solution, which is used for smoke generation.

4.8.3 The smoke generated shall be expose to the supply HEPA filters.

4.8.4 The smoke should gradually flow towards the return end of the system.



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Checking of Airflow Pattern	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.8.5 Observe the smoke pattern.
- 4.8.6 The airflow pattern should ensure that all spaces are within control and specified area is swept efficiently by the airflow, in order to ensure that contamination control is achieved.
- 4.8.7 The smoke should be diffused uniformly from supply grill and pass through return grill/riser.
- 4.8.8 There should not be any short-circuiting of airflow, dead pockets and the flow of air should be unidirectional i.e. from supply to return.
- 4.8.9 Airflow pattern of smoke in LAF unit should be laminar.
- 4.8.10 To check the airflow pattern in different pressure differential area, open the door slightly and hold the glass rod in the adjacent area, which have a positive pressure.
- 4.8.11 Smoke should pass from area under positive pressure to area under negative pressure.
- 4.9 Conducting the Air Flow Pattern by Using the Fogger unit.**
- 4.9.1 Ensure the purified water level in fogger is upto the mark, if required fill the water.
- 4.9.2 Switch on the unit and ensure the red indication for FAN shall glow.
- 4.9.3 After approximate 5 sec, ensure that the green indication for the FOG shall get glow.
- 4.9.4 Connect the suitable accessories like extension pipe with nozzle and the discharge of the unit.
- 4.9.5 Now Fogger is ready to demonstrate the air flow test.
- 4.9.6 The smoke / fog shall get generated and flow shall be adjusted by the potentiometer on the unit.
- 4.9.7 Air flow pattern shall be carried out as mention in point no 4.8.3 to 4.8.9
- 4.9.8 To check the airflow pattern in different pressure differential area, open the door slightly and hold the extension pipe in the adjacent area, which have a positive pressure.
- 4.9.9 Smoke should pass from area under positive pressure to area under negative pressure.
- 4.10 Demonstrate the direction of smoke/fog and photography / videography of the flow pattern shall be taken.
- 4.11 Continue the AHU / LAF for another 10-15 minutes and than handover the area to respective department in coordination with QA.



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Checking of Airflow Pattern	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.12 Frequency:

Air flow pattern checking should be done during qualification / requalification of AHU / LAF and after any modifications in the AHU / LAF or position/design of grilles/risers or cubicle size.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP No. ____: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S) :

AHU : Air Handling Unit.

LAF : Laminar Air Flow.

HEPA : High Efficiency Particulate Air.

QA : Quality Assurance.

TTC : Titanium Tetra Chloride.



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering

SOP No.:

Title: Checking of Airflow Pattern

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	----