PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	**SOP No.:**
Title: Air Velocity Measurement and Calculation of ACPH	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE

To lay down a procedure for Air velocity measurement & Calculation of ACPH.

2.0 SCOPE

2.1 This SOP is applicable for Air velocity measurement & Calculation of ACPH (PAO) test at

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 ISO 14644- 1, ISO 14644- 2 and ISO 14644- 3.

3.1.2 HAS (Health Sciences Authority) 2013.

3.1.3 EU GMP Annex.

3.1.4 WHO technical report series no. 961, 2011 Annex 5.

3.1.5 WHO technical report series no. 961, 2011 Annex 6.

3.2 Attachments

3.2.1 Nil.

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 Acceptance criteria: Measurable terms under which a test results will be considered acceptable.

4.1.2 ACPH: The volume of air supplied to the room in m^3/hr, divided by room volume in m^3.

4.2 Abbreviations

4.2.1 CC : Change Control.

4.2.2 QA : Quality Assurance.

4.2.3 SOP : Standard Operating Procedure.

4.2.4 Sl. No. : Serial No.

4.2.5 HEPA : High Efficiency Particulate Air.

4.2.6 PAO : Poly-Alpha Olefin.

4.2.7 UDAF : Unidirectional Airflow.

4.2.8 ISO : International organization for standardization.

4.2.9 ACPH : Air changes per hour.

4.2.10 AHU : Air Handling Unit.

4.2.11 Avg. : Average

4.2.12 CFM : Cubit foot per minute

4.2.12 Ft^2 : Square feet

4.2.13 Ft^3 : Cubic feet

4.2.14 FPM : Feet per minute

4.2.15 WHO : World Health Organization.

5.0 RESPONSIBILITY:

5.1 Engineering Person:

5.1.1 To follow the SOP for Air velocity measurement & Calculation of ACPH.

5.2 Engineering Head:

5.2.1 To ensure the procedure for Air velocity measurement & Calculation of ACPH is done as per the process defined in the SOP.

5.3 QA Head:

5.3.1 To ensure implementation of the procedure as per SOP.

5.4 Plant Head:

5.4.1 To ensure implementation of the procedure as per SOP.

6.0 Distribution:

I. Quality Assurance

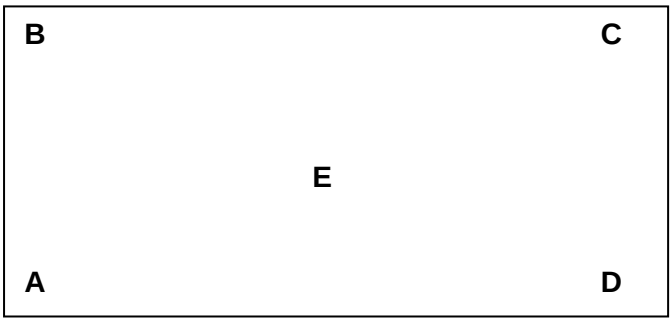
II. Engineering

7.0 PROCEDURE:

7.1 Ensure that the HVAC/ UDAF/ Clean air cabinet is "ON" prior to the start of the test.

7.2 Ensure that the instrument (Vane or hot wire anemometer or flowhood with flowmeter) is calibrated and having a valid calibration certificate.

7.3 Measure the air velocity (FPM) at five different locations of grill / filter at a distance of about 150 to 300 mm (6" to 12 ") as shown below and for laminar air flow units measure the air velocity at working.



7.4 The measuring time at each location should be at least 10 seconds and average reading should be taken. Record the reading in Air Velocity and ACPH test raw data sheet.

7.5 Check the report of external agency and attach the same.

7.6 Calculate the average velocity of the air coming from the supply grill as per following Formula

$$\text{Average Air Velocity (FPM)} = \frac{\text{Reading of (A+B+C+D+E)}}{5}$$

7.7 Calculate the air flow volume at each grill as per the following given below

Air Flow volume (CFM)/Grill =Avg. air Velocity (FPM) x Effective grill area (Ft^2).

7.8 Calculate the total air flow from all the supply grill in the room and add the values to get the total air flow in room (CFM)

Total air flow volume (CFM)/room = Sum of the air flow volume at each supply grill of the room.

7.9 Calculate the number of air changes in the room as per the formula given below:

$$\text{Number of air changes/hour in the room} = \frac{\text{Total Air Flow (CFM) in the room x 60}}{\text{Room Volume } (Ft^3)}$$

7.11 Acceptance Criteria:

Grade / Class of area	Air Velocity	ACPH
A / ISO 5	0.36 to 0.54 m/s (15 – 30 m/s below the filter face) Not less than 0.36 m/s (at working height).	N/A
	72 to 108 FPM (15-30 m/s below the filter face) Not less than 72 FPM(at working height)	
Once in every 6 month	Individual velocity shall be ±20% from the average velocity	More than 20 ACPH based on the criticality of operation OR Client requirement
Once in every 6 month OR once in every year OR based on the Client the HEPA filter requirements but not more than one year		
Once in every year		6 to 20

Note:

A. In case of weighing booth, sampling booth a lower velocity (less than 0.36 m/s) can be used as grade - A condition is not required. Such types of applications are generally called as Air Protection Booth (APB) rather than UDAF and are used to prevent cross contamination not for maintain grade - A requirements

B. In case of tests not meeting the acceptance criteria's following actions shall be take

Stop further testing activities. Immediately inform the client representative.

Re-start the testing activities after corrective actions taken by the client as per client's quality management system and get clearance.

7.12 REQUALIFICATION / REVALIDATION / PERFORMANCE VERIFICATION

Grade/ Class of Area	Frequency	
	Re-Validation	Scheduled
A / ISO 5	In case of any major change / modification in the clean room design OR HVAC / UDAF	Once in every 6 month
B / ISO 6		Once in every 6 month
C / ISO 7		Once in every 6 month OR once in every year OR based on the Client the HEPA filter requirements but not more than one year
D / ISO 8		Once in every year

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			