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PERFORMANCE QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW UNIT

CUSTOMER:

EQUIPMENT:
VERTICAL LAMINAR AIRFLOW UNIT
(____ W x _____ D x _____ H mm)

SUBMITTED BY:

PHARMA ENGINEERS

PLOT NO. 113/A/1, LANE 8, PHASE II,

IDA CHERLAPALLI, HYDERABAD- 500051.

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PERFORMANCE QUALIFICATION PROTOCOL APPROVAL

This document is prepared by the documentation team of **M/S. PHARMA ENGINEERS** for

EQUIPMENT : VERTICAL LAMINAR AIR FLOW UNIT (_____TAG NO)

PLANT /PROJECT :

CLIENT :

Hence this document before being effective shall be approved by **Client / Customer**

M/s. PHARMA ENGINEERS:

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				

CLIENT / CUSTOMER:

	Name	Designation	Signature	Date
Reviewed By				
Approved By				

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1. OBJECTIVE

The objective of this document is to qualify and certify the performance of Vertical LAF (_____TAG NO) with due considerations as specified in DQ of Vertical LAF (_____TAG NO).

2. FILTER INTEGRITY TEST

PURPOSE:

This test is to confirm that the HEPA filter was installed in proper assembly and to ensure that no leakage of air in across the filter gasket & to ensure that the filter is with stated rating

PRE-REQUISITES

1. Gas Generator (Leskin 6 nozzle)
2. Photometer (ATI-2I, ATI-2H & PH -5)
3. PAO (Poly-Alpha olefin) Oil.
4. Compressed air at a pressure of (20 PSI)

TEST METHOD:

1. Percentage of leakage between upstream and downstream is to be confirmed across the filter.
2. Cold gas generator is to be selected to generate upstream concentration, for range 20 to 80 micro grams per liter which is equivalent to millions of particles.
3. Arrangements to be made to maintain consist quantity at the upstream side of the filter.
4. Downstream concentration to be measured with the help of photometer
5. The operation of the instrument is to be followed strictly as per the recommendations of the equipment.

6. Downstream concentration will be displayed in terms of the percentage of leakage, compared to upstream concentration.
7. The allowed percentage of leakage must not be more than filter efficiency.
8. This test is to be conducted for every terminal filter and results to be mentioned in the test data sheet.
9. Care to be taken while conducting the test for selection of oil to generate smoke, which must be non-cacogenic.
10. During the above test, it's recommended to put off the control system of smoke detection.

PERFORMANCE QUALIFICATION (PQ)

Instrument Used			
Name		Make	
Model		Sr. No	
Calibrated On		Calibration Due	

TEST RESULTS

HEPA Filter Identity No	**Upstream Concentration**		**Acceptable downstream (% leakage)**	**Obtained Result in downstream**		**Remarks**
	µg/Ltr	**%**		**From Filter Face**	**From Side Joint**	

ACCEPTANCE:

Percentage of leakage must be less compared to filter efficiency.

However, the acceptance is up to the judgment of experts if any deviations in the readings.

REMARKS (IF ANY):

Test conducted By

Test Witnessed By

3. AIR VELOCITY TEST:

PURPOSE:

This test is to confirm that the equipment is capable of delivering sufficient laminar air velocities in the range of 90 FPM ±20%

PRE-REQUISITES

1. Duly Calibrated Anemometer

TEST METHOD:

1. Make sure that the filter integrity test is completed before the mentioned test.
2. Run the equipment and start measuring the velocity of air from HEPA Filter at 150mm below the filter.
3. Enter the velocity readings in the below sheet.

INSTRUMENT USED			
NAME OF INSTRUMENT		MAKE	
MODEL		SERIAL NO.	
CALIBRATED ON		CALIBRATION DUE ON	

TEST RESULTS		
LOCATION	**VELOCITY READINGS IN FPM 150MM BELOW HEPA FILTER**	**ACCEPTABLE RANGE (FPM)**

ACCEPTANCE

Equipment must deliver and maintain laminar air velocities in the range of 90 FPM ±20%

However, the acceptance is up to the judgment of experts if any deviation in the readings.

REMARKS (IF ANY):

Test conducted By

Test Witnessed By

4. AIRFLOW VISUALISATION TEST

PURPOSE

To ensure that the movement of air in the equipment is not stagnant and flow is moderately conventional air flow.

PRE-REQUISITES

1. Smoke generator
2. Video camera

TEST METHOD:

1. This test is to be performed after completion of perfect air balancing.
2. Place the Smoke generator just below the filter to ensure air is not stringent.
3. Flow visualization has to be checked by generating smoke near the section grille.
4. Smoke movement to be recorded by video camera and the movement of smoke must be towards return grill, ensuring maximum sweep of the equipment.

PERFORMANCE QUALIFICATION (PQ)

INSTRUMENT USED			
NAME OF INSTRUMENT		MAKE	
MODEL		SERIAL NO.	
CALIBRATED ON		CALIBRATION DUE ON	
TEST RESULTS			
EQUIPMENT MODEL	FILTER NO	AIR FLOW DIRECTION	REMARKS

ACCEPTANCE

The flow must be towards return air grill, ensuring maximum sweep of the equipment.
However, the acceptance is up to the judgment of experts if any deviations in the readings.

REMARKS (IF ANY):

Test conducted By

Test Witnessed By

5. PARTICLE COUNTING

PURPOSE

To check the correct functioning of the equipment with respect to filtration efficiency, by measuring the particle concentration at 0.5 micron as per ISO-14644-1 (2015).

PRE-REQUISITES

1. Particle counter with duly calibrated

TEST METHOD:

1. Test to be conducted while the Equipment is at rest condition i.e. its running at the ideal condition.
2. Particle counter must be having valid calibration certificate.
3. Particle counter must have minimum of 1.7 Cfm capacity.
4. Particle counting must be verified at 0.5 micron only.
5. Number of locations and place of location to be decided before conducting the test.
6. Drawing is to be prepared showing the locations of the particle counting and same drawing is to be attached along with the particle count report.
7. The print out of the particle counter must specify the location number, time interval and sampling time, other than the concentration of particles.
8. All the print outs are to be attached along with this as a test data sheets and it must be signed by the person who had conducted the test as well as person who witnessed the test.

PERFORMANCE QUALIFICATION (PQ)

INSTRUMENT USED			
Name		Make	
Model		Serial Number	
Flow rate		Sampling Time	
Calibrated On		Calibration Due on	

TEST RESULTS			
Equipment Name	**Location ID**	**Average No. of Particles ≥ 0.5 µm/m3**	**Average No. of Particles ≥ 5 µm/m3**
Mean Average			

CERTIFICATION RESULTS AS PER ISO14644 -1 (2015)		
CLASS ISO 5 AT REST	Maximum number of particles allowed per cubic meter of air	
	0.5µm	5µm
	3520	29

ACCEPTANCE

Particle concentration should comply with ISO-14644-1(2015) standards.
However, the acceptance is up to the judgment of experts if any deviations in the readings.

REMARKS (IF ANY):

Test conducted By

Test Witnessed By