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HVAC VALIDATION IN ORAL SOLID DOSAGE FACILITY AND IT'S SIGNIFICANCE IN PHARMACEUTICAL INDUSTRY

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ABSTRACT:

HVAC system is a major requirement of anydrug manufacturing facility. ... Heating, Ventilation and Air Conditioning is a system which controls the air temperature by controlling the air filtration and the moisture present in the air.

A pre-defined Protocol/ mechanism is used For Qualification / Requalification of Air Handling Unit / System (AHU). It describes the procedure for different tests parameters, acceptance criteria, re-qualification criteria and other documentation to be used for requalification of Air handling unit (AHU) serving to manufacturing area of Drug Product.

Procedure for validation of HVAC system and details of tests in pharmaceutical industry: Air Flow Pattern, Air Flow Velocity & Change Per Hour, Filter Leak Test, Particles Count Test; Viable & Non-Viable Monitoring, Filter Integrity Test (PAO Test), Pressure Difference, Recovery, Temperature and Humidity Uniformity Test

HVAC System is the Heating Ventilation Air Conditioning System which is implied in the Pharmaceutical industry with a purpose to achieve the desired environmental conditions specific for the products manufacturing and humans' exposure.

Qualification of HVAC system is conducted and based on the results Facility declared fit for pharmaceutical production of Drug substances, HVAC system is qualified.

Keywords: Validation, AHU qualification, HVAC Qualification, Installation qualification, Operational qualification and performance qualification.

INTRODUCTION:

HVAC system is vital part of any Pharmaceutical manufacturing system and qualification of HVAC system in an oral solid dosage, sterile, non- sterile facility hugely impacts the formulation activities during drug processing.

HVAC system is qualified on annual basis driven through protocol. Based on protocol, Design, Installation, Operation and Performance Qualification is performed and after obtaining satisfactory results as per the protocol and with

respect to Regulatory Guidelines required for the facility. Activity of drug manufacturing can be started.

The test parameters are as such air flow velocity, air flow pattern, ACPH, filter leakage test, particle count, viable particle count, filter integrity test and pressure differential. Also recovery test for temperature and humidity, temperature and humidity uniformity.

When results are obtained within the acceptance criteria and all the results are documented. Then HVAC qualification is completed. HVAC qualification carried out as pre-determined protocol is the basic requirement for HVAC validations

After HVAC qualification only, Drug manufacturing Pharmaceutical industry clears the regulatory standards and gets approval for manufacturing. Drug manufacturing permission is received once HVAC system is qualified.

System Description:

The HVAC system consist with the following components and parts-

A. Air supply equipment,
B. Air Cooling & heating system,
C. Air distribution network,
D. Air filtration system,
E. Dehumidification system,
F. Instrumentation & control system.

The HVAC system is further divided into two categories:

I. Air handling units
II. Dehumidifiers

- **Air supply equipment:** The air supply equipments in the air handling unit is the blower.

The blower is provided in the unit to supply air in the working area. This blower is belt driven by a motor. The blower takes the air from the rooms as return air and delivers it to the working areas.

Air cooling and heating system:

The Air-Handling units are provided with DX coils in which Freon gas flows directly. Temperature control is vital in an air handling unit. The major components of this system are compressor, air-cooled condenser, expansion valves and evaporator coil. Air passes through DX coil and in turn gets cooled. Another factor/parameter while in AHU is humidity. A humidity comfort level in the range of 45% – 55% relative humidity (RH) should be maintained.

- **Air Distribution Network:**

A separate air distribution system is provided to supply the air delivered by the blowers into the processing areas. A ducting network of GI sheets is being provided with volume control dampers in the supply and return air ducts in each room.

- **Filtration system:** Filters are provided at different locations to arrest the contamination of air. The return air from the room is first passed through the 10 micron filter after entering the air-handling unit.it is then passed through a 3-micron microbe filter provided in the plenum/in the AHU and Finally terminally mounted 0.3 micron HEPA filters before entering into the working area.

- **Instrumentation and Control system:** The DX unit of the Air Handling Unit is controlled through digital temperature controller. A DX system the Freon gas that flows in the evaporator coils cools the air directly. This evaporator coil is mounted inside the air-handling unit.

HEPA Filters

High efficiency particulate air (HEPA) filters are used. They maintain the required condition in the working area. The efficiency and integrity of the filters that are used in this system must be checked at regular intervals by performing leak test. HEPA filters are 0.3 micron filter with 99.97% efficiency. This type of air filter can theoretically remove **at least 99.97%** of dust, pollen, mold, bacteria, and any airborne particles with a size of 0.3 microns (µm).

FUNCTIONING:

The Air Handling Unit treats the air by filtering, cooling / heating, humidifying / dehumidifying. The basic function of the AHU is take in outside air, re-condition it and supplies it as fresh air to a building.

The main function of the AHU is to deliver filtered air in the respective cubical to achieve desired clean room class. HVAC system takes the atmospheric air which will be filter through 10-micron, filter installed at fresh air inlet damper. Filtered air then passes through Box type Pre filter (MERV-08) of 10-micron with efficiency of 90% to eliminate airborne particles. This filtered air further passes through flange type fine filter (MERV-10) of 5 microns with efficiency of 95%. Further this filtered air passed through the blower section. This filtered air further passes through flange type Super fine filter (MERV-13) of 3 microns with efficiency of 99%

Hot water (HW) coil are provided to maintain the air temperature as required.

Final filtration to be by Terminal mounted HEPA filter of H-14 grade, rating 0.3-micron efficiency of 99.997%. Drain point is provided near the heating coil for drain GI ducting is provided to carryout supply air and return air form the respective cubicle.

There are various sub components of Air Handling Units

1) **Inlet section**-This section is having air inlet to air handling unit
2) **Mixing section**- This section consists of Mixing Box with manually operated fresh & return air aluminum dampers.
3) **Fan/Blower Section**- This section consists of imported plug type direct driven fan & motor to achieve desired CFM.
4) **Filter section**- This section consists of 50mm thick Box type Pre Filter, Fine filter and Super fine filter 305mm thick Flange type.
5) **Coil section**- This section consists of coil section with multi-rows deep DX coil& hot water type heating coil

Functional mechanism:

The purpose of Air Handling Unit is by circulating & then conditioning air flow. This can be achieved by cooling, heating & ventilation the unit to supply filtered air for maintaining desired clean room class, temperature & relative humidity in the working areas.

INSTALLATION QUALIFICATION

1.0 **Pre-requisite of Installation-Qualification:**

1.1 Document Detail:

Sr. No.	Document Name	Available/ Not Available
1.	Copy of Purchase Order	**Available**
2.	Installation & Operational Manual	**Available**
3.	Test Certificates of DX Coil.	**Available**
4.	Test Certificates of Hot Water Coil.	**Available**
5.	Technical Data sheet	**Available**
6.	Test certificates of Filters	**Available**

2.0 Equipment Drawing:

Sr. No.	Document Name	Available/ Not Available
1.	General Arrangement Drawing	**Available**
2.	P & I Diagram	**Available**
3.	Schematic diagram	**Available**

3.0 Detail of the Equipment Being Qualified:

Equipment Name	Manufacturer	Equipment ID No.
Air Handling Unit	Edgetech Air Systems Pvt Ltd	As per protocol

4.0 **Installation Qualification Procedure:**

- Identify the critical components of equipment and verify that the components are complying as per desired specifications. Record the observations in the data sheet.
- Verify the MOC of the component as per the instructions Record the observations of the MOC in the Data Sheet. However, in case the MOC certificate is provided by the manufacturer, the MOC test can be considered as optional.
- Identify the utility supplies required for equipment operation. Verify that the utilities are as per the specification mentioned. Record the observation in the Data Sheet of section.
- Identify the critical instruments supplied with the equipment or installed properly as per general arrangement drawing.
- Verify that instruments are as per the design specifications. Review the calibration status of the instruments. Record the availability of the calibration record.
- To verify the proper assembly of the components as per the equipment drawings. Record the installation location and verification of assembly in observation.
- List the available drawing and record the ref. no. for their location / availability in observation.
- Identify the SOPs and record the SOP title.
- Record the deficiency (if any) in respective section
- Check the physically wherever installation of components to be verified. Take the reference from design qualification and certificates wherever dimension, calibration, MOC are applicable.

- **Installation Verification for Safety Features:**

Identify, whether the safety features has been done. Record the verification of safety feature in table given below

Sr. No.	Description	Acceptance Criteria	Observations
Safety Features			
a.	Earthling	Shall be provided to Motor, Cabinet & Panel.	Done
b.	Electrical wiring	No loose wires. All wires well insulated, tagged & supported.	Done
c.	Interlocking (Limit Switch)	AHU should Stopped working automatically if access door open.	Done

- **Acceptance Criteria:**

Following shall be the acceptance criteria for design qualification of the equipment;

- ✓ The air handling unit should be fabricated as per approved user requirement specification.
- ✓ All the component and support utilities should be available as per the approved design specification and manufacturer recommendations.
- ✓ All drawings should be available as per the approved URS and design specification.
- ✓ All support components should be intact and in operative condition.
- ✓ Any deviation from the acceptance criteria of the specific check points shall be reported and decision shall be taken for the acceptance, rejection, replacement or rectification of the equipment/system. Corrective actions shall be documented.

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OPERATIONAL QUALIFICATION

1.0 Pre Requisite of Operation Qualification: The following documents shall be available before staring the operation qualification.

Sr. No.	Document Name	Available/Not Available
1.	Installation Qualification Report	**Available**
2.	Draft SOPs	**Available**
3.	Installation, Operation and Maintenance Manual	**Available**
4.	Calibrated tachometer (ID. No.....) (*attach calibration certificate with operation qualification report)*	**Available**
5.	Calibrated anemometer (ID. No.....) (*attach calibration certificate with operation qualification report)*	**Available**

2.0 Reference Draft SOPs:

Sr. No.	Particulars	Available/Not Available
1.	Operation	**Available**
2.	Preventive Maintenance	**Available**
3.	Filter cleaning & replacement	**Available**

3.0 Instrument Calibration Review: Instruments calibration status shall be reviewed prior to operation of equipment to assure that equipment is working consistently with its tolerance range. Instrument Calibration shall be reviewed as per Annexure-I.

4.0 Training of Personnel: Training on equipment Operation shall be imparted to all concerned person after operation qualification and record shall be attached with Operation Qualification report.

5.0 Acceptance Criteria:

- The critical process control instruments shall be calibrated.
- The equipment shall be operating while operated as per its specified operating parameters.
- The safety features are functioning as per its specified instruction.
- SOPs are complying as per the operating principle of the equipment.

6.0 Key Functionality Verification: (Control Panel)

Sr. No.	Description	Acceptance Criteria	Observation
1.	Turn ON main switch of main electric panel	Red, Yellow,Green light on Electrical Panel should glow	complies
2.	Cut OFF main power supply	Red, Yellow, Green light on Electrical Panel should off.	complies

7.0 Operation and functional Test:

Sr. No.	Description	Acceptance Criteria	complies
1.	Put Selector Switch (VFD) on **Auto** Mode	VFD should run of the blower.	complies
2.	Put Selector Switch (VFD) on **Off** Mode	VFD should stop of the blower and yellow light should glow on panel.	complies
3.	Put Selector Switch (VFD) on **Manual** Mode	VFD should Run from VFD keypad instead of Selector switch on Panel.	complies
4.	Put Selector Switch (Outdoor) on **Auto** Mode	Outdoor should run of as per set temperature and RH Value .	complies
5.	Put Selector Switch (Outdoor) on **Off** Mode	Outdoor should OFF.	complies
6.	Blower Working	It Should be Smooth without any abnormal noise	complies
7.	Fresh Air Damper	Shall be-Manually adjustable. Should be Smooth in operation	complies
8.	Supply Air Damper	Shall be-Manually adjustable. Should be Smooth in operation	complies
9.	Return Air Damper	Shall be-Manually adjustable. Should be Smooth in operation	complies
10.	Exhaust Air Damper	Shall get fixed at any point & shall not get dislocated during normal AHU run	complies
11.	Control Panel	Shall be operational & functional	complies

8.0 HEPA Filter Integrity test:

8.1 The filter integrity test shall be performed by qualified and trained person only.

8.2 Measuring and testing instrument being used shall be calibrated with reference to NPL/NABL traceable reference standard.

8.3 Filter integrity testing shall be performed after operational velocities have been verified and adjusted where necessary.

8.4 Poly alpha olefin (PAO) shall be used for the generation of particles/ fumes. MSDS of the poly alpha olefin shall be provided by the external agency which is used during the execution of HVAC validation.

8.5 Position the aerosol generator such that aerosol is produced into the upstream of the subjected HEPA filter.

8.6 Provide compressed air to the fume generator at pressure of 1.5-2 kg/cm2.

8.7 The concentration of the aerosol challenge upstream of the filter should be between 20 mg/m^3 and 80 mg/m^3.

8.8 A concentration lower than 20 mg/m^3 can reduce the sensitivity of leak detection. A concentration greater than 80 mg/m^3 can cause excessive filter fouling over the extended test period which can result odd.

8.9 Scan the upstream concentration and set photometer 100%.

8.10 Scanning should be performed over the entire downstream face of the each filter, the perimeter of each filter, the seal between the filter frame and the grid structure, including all the joints at the distance of approximately 3 cm from the downstream filter face or the frame structure during activity execution.

8.11 The probe traverse scan rate when using 3 cm x 3 cm square probe should not exceed 5 cm/s with a rectangular probe, the maximum area scan rate should not exceed $15cm^2/s$.

8.12 While scanning, any indication of leak equal to or greater than the limit which characterizes a designated leak should be cause for holding the probe at the leak location. The location of the leakage should be identified by the position of the probe that sustains the maximum reading on the photometer during the testing.

8.13 Measurement of the aerosol upstream of the filters should be repeated at reasonable time intervals between and after scanning for leaks, to confirm the stability of the challenge aerosol concentration.

Acceptance Criteria: The penetration of the HEPA filter should not be more than rated efficiency of the filter which is 0.01%. as per the regulatory standards. (ISO 14644-1& WHO TRS 961) .

9.0 Particle count:

9.1 The particle count test should be performed by qualified and trained person only.

9.2 Measuring instrument being used should be calibrated with reference to NPL/NABL traceable reference standard.

9.3 Ensure that the sampling locations should be evenly distributed throughout the area of the clean room.

9.4 Sampling location should be identified as per given table.

Area of cleanroom (m^2) Less than or equal to	**Min number of sample locations to be tested NL**	**Area of cleanroom (m^2) Less than or equal to**	**Min number of sample locations to be tested NL**
		5	5
		04	6
		08	7
		16	8
10	5	148	19
24	6	156	20
28	7	192	21

Equation A.1: N = 27 [A/1000]

10.0 The volume sampled at each location should be at least 2 litres, with a minimum sampling time at each location of 1 minute. The sampling probe should be positioned at working level and air flow probe should be directed vertically upward.

Acceptance Criteria: All the clean rooms should comply as per the regulatory standards &designed class at rest as per ISO 14644-1 & WHO TRS 961.

11.0 Viable Air Microbial Count (Bio burden):

As per SOP for Environment monitoring for Bio burden in manufacturing Area SOP

Acceptance Criteria:

Grade D - BySettle plate Method for Grade "D" (Class 100000) NMT 100 CFU/ 4hours and by air sampler method for Grade "D" (Class 100000) NMT 200 CFU/ m^3

Grade C- BySettle plate Method for Grade "C" (Class 10,000) NMT 50 CFU/ 4hours and by air sampler method for Grade "C" (Class 10,000) NMT 100 CFU/ m^3.

12.0 Recovery Test:

12.1 The recovery test shall be performed by qualified and trained person only.

12.2 Measuring instrument being used shall be calibrated with reference to NPL/NABL traceable reference standard.

12.3 Locate the particle counter in the highest particle count location identified in particle count test.

12.4 Switch "off" air handling unit of the room under test and adjacent rooms.

12.5 Start particle counter and take sample till particle count reaches beyond the acceptance criteria.

12.6 Evaluate the hold time that subjected area will remains with clean room class.

12.7 When the particle count level reaches more than the specified class limit, switch "ON" the Air Handling Unit of the room and adjacent rooms immediately. Switch on the particle counter.

12.8 Record the particle count each minute until the cleanliness level in the room is restored to the original condition& recorded the recovery time.

Acceptance Criteria: Hold time shall be established. The recovery time for the mentioned test should not be more than 15 minutes.

13.0 Air Flow Pattern:

13.1 The air flow pattern test shall be performed by trained and qualified person only.

13.2 Ensure area should be in rest condition and all equipments are covered before starting test.

13.3 Switch on the fogger. Wait till smoke comes out.

13.4 Place outlet of fogger near supply grill and ensure that smoke should be sufficient for visualization.

13.5 Record the room name, room identification number and differential pressure reading on measuring device (if applicable).

13.6 Record the air flow pattern and direction through video camera, gradually move fogger outlet from supply to return air grill and record the same.

13.7 To check and record pressurization, open door slightly and move fogger outlet near doors.

13.8 Ensure air should move from high pressure zone to lower.

13.9 Ensure recording should be sufficient to demonstrate the air flow direction and pattern.

Acceptance Criteria: Smoke should flow through all these critical areas in uniform and unidirectional pattern as per the standards. If the smoke returns or flows back due to turbulence, system cannot be accepted and must be rebalanced or readjusted as per the guidelines.

14.0Re-qualification criteria:

The AHU System shall be subjected to requalification under following conditions: -

14.1The air handling unit system is not performing within the pre-defined acceptance criteria.

14.2If any of the test results are not within the limits defined in the acceptance criteria.

14.3If any critical component or modification of air handling unit is replaced due to technical problem.

14.4Due for re-validation as per below defined frequency:

Sr. No.	Test Parameter	Re-validation Period	Frequency
1.	Integrity test for HEPA filter	Yearly	± 15 Days
2.	Air flow pattern	Yearly	± 15 Days
3.	Velocity and air changes	Six month	± 15 Days
4.	Non-viable particulate count	Six month	± 15 Days
5.	Recovery test (non-viable particle count, pressure differential, temperature and relative humidity.)	Yearly	± 15 Days
6.	Viable count (microbial monitoring) *	Routine monitoring as per SOP	As per SOP
7.	Pressure Differential*	Routine Monitoring as per SOP	As per SOP

*Remark: Since all the parameters i.e. viable count, pressure differential, are routine parameters and being monitored and recorded. Hence this methodology is followed during the execution of HVAC Validation.

RESULT: Results are compiled by collecting all the data of HVAC validation. All the tests performed for qualification of HVAC need to comply with the standards and guidelines for Oral solid dosage form in Pharmaceutical Industry.

DISCUSSION: HVAC qualification is done based on the protocol cum report. This report is prepared on the basis of the results obtained during the testing of HVAC. After performing all the tests and receiving of the data. Results are verified by QA department and approved report is prepared as per the below mentioned format

1. Approval:

Signing of this approval page of HVAC validationreport0 indicates agreement with the re-validation approach described in this document. Any changes in the validationreport, change control procedure shall be followed.

2. Objective:

The objective of this report is to verify the fulfilment of the given below requirements:

- To provide the guidelines for performing the tests during re-validation of the AHU system having at its defined frequency.
- To verify that AHU system is performing well within the specified limits.
- AHU system along with its major components are capable of maintaining desired set of environmental conditions suitable for the manufacturing, reliable and consistently when operated as per the established procedure.

3. Scope:

Scope of this re-validationreport is applicable for the performance of the AHU system installed at service floor to supply controlled air at Tirupati Medicare Limited Paonta Sahib.

4. Responsibilities:

The HVAC validation teamconsist of a member from each of the following departmentsand shall be responsible for the overall compliance with this protocol and the activity shall be carried out as per the pre-defined protocol;

4.1 Engineering:

4.1.1 Execution of re-validation activity.

4.1.2 Review of re-validation protocol and report.

4.1.3 Providing technical guidance and instructions to the validation team involved in revalidation activity.

4.2 External Agency:

4.2.1 Carry out air velocity, HEPA filter integrity, particle count, recovery test, air flow pattern test.

4.2.2 Submit the test certificate and its master calibration certificate of instrument used for above test.

4.2.3 Submit the training certificate of the personnel carry out the tests.

4.3 Production:

4.3.1 Support the engineering personnel during execution of re-validation activity.

4.3.2 The review of re-validation protocol and report.

4.4 Quality control:

4.4.1 To carry out microbial count activity and preparation of report.

4.4.2 Review of re-validation protocol and report.

4.5 Quality Assurance:

4.5.1 Prepare, review and approve of re-validation protocol and report.

4.5.2 Provide technical guidance during re-validation activity.

4.5.3 To execute re-validation protocol.

4.5.4 Verify that the HVAC system is performing well within the acceptance criteria.

5. System Description:

The HVAC system consists of:

- ✓ Air supply equipment,
- ✓ Air Cooling & heating system,
- ✓ Air distribution network,
- ✓ Air filtration system,
- ✓ Dehumidification system,
- ✓ Instrumentation & control system.

The HVAC system is further divided into two categories:

- ❖ Air handling units,
- ❖ Dehumidifiers.

There are various sub components of Air Handling Units

Blower: One number of blowers is provided in the unit to supply air in the working area. This blower is belt driven by a motor. The blower takes the air from the rooms as return air and delivers it to the working areas.

Cooling Coil: Air-Handling units are provided with DX coils in which Freon gas flows directly. The major components of this system are compressor, air-cooled condenser, expansion valves and evaporator coil. Air passes through DX coil and in turn gets cooled.

i) **Air Distribution Network:** An air distribution network is provided to supply the air delivered by the blowers into the working areas. A ducting network of GI sheets is being provided with volume control dampers in the supply and return air ducts in each room.

ii) **Filtration system:** Filters are provided at different locations to arrest the contamination of air. The return air from the room is first passed through the 10 micron filter after entering the air-handling unit.it is then passed through a 3-micron microbe filter provided in the plenum/in the AHU and Finally terminally mounted 0.3 micron HEPA filters before entering into the working area.

iii) **Instrumentation and Control system:**

- DX unit of the Air Handling Unit is controlled through digital temperature controller.
  A DX system the Freon gas that flows in the evaporator coils cools the air directly. This evaporator coil is mounted inside the air-handling unit.

6. Abbreviation:

Abbreviation	Full Form	Abbreviation	Full Form
HVAC	Heating Ventilation air conditioning	NPL	National Physical Laboratory
HEPA	High Efficiency Particulate Air	NMT	Not More Than
%	Percentage	NLT	Not Less Than
CFM	Cubic Feet per minute	FPM	Feet per Minute
m^3	Cubic meter	No.	Number
ft^3	Cubic feet	RH	Relative Humidity

Abbreviation	Full Form	Abbreviation	Full Form
°C	Degree Celsius	RVR	Re-Validation Report

7. Summary:

_Based upon the All the Results obtained during the execution of HVAc validation study. It is concluded that all the test parameters complies the regulatory standards and no anomaly observed during the report compilation.

All the test parameters such as :

Integrity test for HEPA filter

Air flow pattern

Velocity and air changes

Non-viable particulate count

Viable count (microbial monitoring)

All the above mentioned test are passed and no deviation observed during the validation of HVAC.

The HVAC system is marked capable/ in capable to produce the desired results.

It is safe to manufacture the Product in the area where the HVAC system is installed and environmental conditions are well within the limit.

Significance of HVAC validation in pharmaceutical industry is very high.

No regulatory agency allows the manufacturing of Drug products without installation of HVAC in the manufacturing Unit.

Conclusion: Below is the conclusion details and result compilation of the test performed. It is concluded that HVAC installed is in working condition and is capable to provide Class D environment. All the test results comply as per ISO 8.

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Test results attached.

AIR VELOCITY TEST REPORT (ANNEXURE-I)

Occupancy State	At Rest		
Test Date	06/07/2022		
Room Details			
Area Name/Code	**Class**	**Volume [Ft³]**	**Number Of Supply Grill**
Filling Area (AFL03)	D (ISO-8)	7137.47	03
Test Carried By			
Name	Sandeep Sharma	**Training Certificate**	Attached
Instrument details			
Instrument Name	**Serial No.**	**Make**	
Digital Anemometer	463786	LUTRON	
Model No.	**Calibration Date**	**Due Date**	
AM-4201	25/11/2021	24/11/2022	

Test Observation Details

Room Name / No.	**Filter I.D.**	**Velocity Readings fpm No. of Cycles : 5**					**Avg FPM**	**Grill Size**	**Room Volume**	**CFM**	**ACPH**
		1	**2**	**3**	**4**	**5**	**[fpm]**	**[ft²]**	**[ft³]**	**[cfm]**	
Filling Area (AFL03)	ENG/AUT01/AHU02/HF-02	200	197	185	199	200	196	4.00	7137.47	784.80	23

	ENG/AUT01/AHU 02/HF-03	240	260	251	245	235	246	4.00		984.80
	ENG/AUT01/AHU 02/HF-04	219	235	241	255	219	234	4.00		935.20
								Total CFM =		**2704.80**

Observed ACPH	**23**
Acceptance Criteria	**NLT 20 ACPH**
Remarks	**Above Test Complies With Acceptance Criteria As Per ISO-14644 & WHO TRS**

Sign.& Date:	**Sign.& Date:**	**Sign.& Date:**

PARTICLE COUNT TEST REPORT (ANNEXURE-Ill)

Occupancy State	At Rest		
Test Date	06/07/2022		
Room Details			
Area Name/Code		**Class**	**Number Of Sampling Point**
Filling Area (AFL03)		D (ISO-8)	12
Test Carried By			
Name	Sandeep Sharma	**Training Certificate**	Attached
Instrument details			
Instrument Name	**Serial No.**	**Make**	
Particle Counter	62483	Lasair	
Model No.	**Calibration Date**	**Due Date**	
Lasairlll/5100	17/09/2021	17/09/2022	

Test Observation Details

Room Name/ No.	**Location Id.**	**No. Of Particles Per M^3**	
		>= 0.5 micron	**>= 5.0 micron**
Filling Area (AFL03)	1	858784	7585
	2	615487	5032
	3	523458	9458
	4	745852	7582
	5	416528	6458
	6	662458	9548
	7	458213	3345
	8	325148	2654

	9	489016	3625
	10	785126	5564
	11	348540	5245
	12	629548	2365
Average		**571513**	**5705**
Acceptance Limit		**3520000**	**29000**

Acceptance Criteria :	**Clean Room Specifications As Per EU-GMP & WHO TRS**
Remark:	**Above Test Complies With Acceptance Criteria**

FILTER LEAKAGE TEST REPORT (ANNEXURE-II)

Occupancy State	At Rest
Test Date	06/07/2022

Room Details

Area Name/Code	**Class**	**Number Of Supply Grill**
Filling Area (AFL03)	D (ISO-8)	03

Test Carried By

Name	SahilVerma& Rahul Sharma	**Training Certificate**	Attached

Instrument details

Instrument Name	**Serial No.**	**Make**

Aerosol Photometer	92978	TEC Services
Model No.	**Calibration Date**	**Due Date**
PH-5	19/01/2022	19/01/2023

Test Observation Details

Room Name	Filter I.D. / Grill I.D.	Upstream Concentration in (µg/l)	Downstream Leakage in (%)	Set Upstream Conc.%	Remark
Filling Area (AFL03)	ENG/AUT01/AHU 02/HF-02	32	0.0018	100%	Pass
	ENG/AUT01/AHU 02/HF-03	31	0.0015	100%	Pass
	ENG/AUT01/AHU 02/HF-04	28	0.0009	100%	Pass
Acceptanc Criteria:	**NMT 0.01% Downstream Concentration and 20 to 80 upsterm concentration**				

Remark:	**Above Test Complies With Aceptance Criteria As Per ISO -14644 & WHO TRS**

Recovery Time Test Reports (ANNEXURE-IV)

Occupancy State	At Rest		
Test Date	06/07/2022		
Room Details			
Area Name/Code	Filling Area (AFL03)	**Class**	**D (ISO-8)**
Test Carried By			
Name	Sandeep Sharma	**Training Certificate**	Attached

Instrument details

Instrument Name	**Serial No.**	**Make**
Particle Counter	62483	Lasair
Model No.	**Calibration Date**	**Due Date**
Lasairlll/5100	17/09/2021	17/09/2022

Test Observation Details

Room Name/ No.	**Counts exceeds and Recovery Time**	**Time HH:MM:SS**	**No. Of Particles Per m^3**		**AHIU ON/ OFF**
			>= 0.5 micron	**>= 5.0 micron**	
Filling Area (AFL03)	Initial count	10:50:05	987264	12501	AHU ON
	Time at which counts exceeded against the designed class	10:51:05	----------	----------	AHU OFF
		10:56:22	8594562	795458	AHU ON

	limit	10:57:22	6254874	584682	
		10:58:22	5264574	485463	
		10:59:22	4426158	268457	
		11:00:22	3945824	86584	
		11:01:22	2458450	56245	
		11:02:22	945824	35791	
	Time at which counts reaches below the designed class limit	11:03:22	886954	12940	
Time taken to Recover the designed class :	00:08:00				
Recovery Time	**00:08:00**				
Acceptance Criteria	**Area Should Be RecoverdWith in 15 Min**				
Remark:	**Above Test Complies With Acceptance Criteria As Per ISO -14644 & WHO TRS**				

CONCLUSION

After performing the tests and HVAC system qualification as per the required protocol it was observed that the designed AHU achieves the required results and objective of performance qualification is met with the HVAC system of all the area and is suitable for routine intended use as established by carrying out intended experiments and complies the results with the predetermined acceptance criteria (limits) after which the HVAC system is ready for routine use by qualified personnel.

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Acceptance criteria: NMT 0.01% (ISO 14644-3 & WHO TRS 961)

B. Particle Count Test :

Acceptance Criteria: As per ISO 14644-3 & WHO TRS 961

C. Air Velocity and Air changes :

Limit ACPH: NLT 30 ACPH (±20% ACPH of Designed ACPH)

D. Recovery test :

Acceptance Criteria: As per ISO 14644-3 & WHO TRS 961

E. Air Flow Pattern Test:

Air should flow in uniform and unidirectional pattern.

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