Unit: Unit VII

AHU/Ventilation No.: AHU-04 **Date of Start:**12.08.2025

1.0 Objective:

To establish that the HVAC system is performing as it is supposed to perform by:

1.1 Ensuring that the required temperature, relative humidity and pressure gradient is within the limit of acceptance criteria (if applicable).

1.2 Ensuring that the quality of air with respect to non-viable (particulate matter count) is within the limit of acceptance criteria (if applicable).

1.3 Ensuring that the total number of air changes, Velocity and Installed filter leakages are within the limit of acceptance criteria (if applicable).

1.4 Ensure that the airflow direction and visualization is as per requirement (if applicable).

2.0 Justification for selection of system:

Sample Justification

3.0 Scope:

Applicable to all AHU/Ventilation System which is installed to control room conditions.

4.0 Site of study:

Site and location Name	Cipla Unit VII, Goa
Department Name	Production
HVAC Scope	Compression I

5.0 Performance verification Team And Responsibility As Per Performance verification Documents:

Representative From:

User Department	No Approval Required
Engineering	Engg User One
EHS	No Approval Required
Quality Control	No Approval Required
Quality Assurance	No Approval Required

6.0 Description of the system to be verified:

To establish that the HVAC system is performing as it is supposed to perform by:

1. Prior to initiation of test, intimation to the respective department, suitable operation of HVAC unit and operation of supply and exhaust unit, if applicable etc.

2. Specify 'NA' wherever not applicable / if other than given specification mention separately.

3. The acceptance criteria for non-viable particle count should be considered as per ISO/EU/WHO/USFDA guideline.

Area	:	Compression I	
Equipment No.	:	AHU-04	
Type of AHU/Ventilation recorded in	:	Recirculating	
Previous verification/Qualification done on	:	NA	
Design Capacity in CFM.	:	675	
Classification of Area catered by HVAC system and particle count occupancy state at which class is achieved.	:	At Rest	In Operation
		ISO-8	Not defined
Filtration			
Fresh air filter (if applicable)	:	Treated fresh air through 3µ filter provided	
Intermediate	:	EU-6	
Pre filter (if applicable)	:	EU-4	
Fine filter (Supply)	:	EU-8	
Exhaust Pre filter (if applicable)	:	NA	
Exhaust final Filter (if applicable)	:	NA	
Terminal filter (If applicable)	:	EU-13	
Bag in Bag out filter (If applicable)	:	EU-13	
Relief filter	:	EU-13	
Filter on Return riser	:	EU-4	
Terminal Filter on Riser	:	EU-4	
Reactivation Filter	:	EU-4	

7.0 Standard Operating Procedures (SOPs) and Microbiological methods (MMs) to be followed:

Sr. No.	SOP/Document Name	SOP/Document No. Including Version No.	Data Entered by Sign & Date
1.	SOP for operating the HVAC System	na	Engg User One 12.08.2025 12:20:18
2.	SOP for recording pressure difference with respect to adjacent area / atmosphere.	na	Engg User One 12.08.2025 12:20:18
3.	SOP for Air velocity measurement and calculation of number of air changes	na	Engg User One 12.08.2025 12:20:18
4.	SOP for checking installed filter system leakages	na	Engg User One 12.08.2025 12:20:18
5.	SOP for checking of particulate matter count.	na	Engg User One 12.08.2025 12:20:18
6.	SOP for airflow direction test and visualization.	na	Engg User One 12.08.2025 12:20:18
7.	SOP for BMS start stop operation. (if applicable)	na	Engg User One 12.08.2025 12:20:18
8.	SOP for Duct leakage Measurement.	na	Engg User One 12.08.2025 12:20:18
9.	SOP for area recovery / clean up period study.	na	Engg User One 12.08.2025 12:20:18
10.	SOP for containment leakage test.	na	Engg User One 12.08.2025 12:20:18
11.	SOP scrubber / Point exhaust CFM	na	Engg User One 12.08.2025 12:20:18
12.	Microbiological method (MM) for environmental monitoring	na	Engg User One 12.08.2025 12:20:18
13.	Additional SOP Details	na	Engg User One 12.08.2025 12:20:18

8.0 Controls

8.1 Ensure the calibration details of instrument used for performance

8.2 Training should be available for concerned persons.

Name	Department	Training Status
Engg User One	Engineering	Trained
QA User One	Quality assurance	Trained

8.3 Ensure that all required precautions should be taken as per operation SOP.

8.4 Gowning procedure used by personnel should be as per area requirement.

9.0 Verification Procedure:

<table>
<tr><td rowspan="3">1.</td><td>Test</td><td>Number of air changes per hour in the area.</td></tr>
<tr><td>Acceptance Criteria</td><td>
<table>
<tr><th>Sr No.</th><th>Area</th><th>Air change per hours</th></tr>
<tr><td>1</td><td>ISO Class 8</td><td>More than 10</td></tr>
<tr><td>2</td><td>ISO Class 7</td><td>More than 20</td></tr>
<tr><td>3</td><td>ISO Class 5</td><td>More than 30</td></tr>
<tr><td>4</td><td>Controlled Not Classified (CNC)</td><td>More than 06</td></tr>
</table>
</td></tr>
<tr><td>Observations</td><td>Pass
Test Performed by External Vendor: Test Vendor Three</td></tr>
<tr><td rowspan="3">2.</td><td>Test</td><td>Fresh air quantity in CFM</td></tr>
<tr><td>Acceptance Criteria</td><td>Should not be less than 10% of area CFM</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">3.</td><td>Test</td><td>Return air CFM at diffuser / riser / riser filter in the area (if applicable)</td></tr>
<tr><td>Acceptance Criteria</td><td>To be checked at actual for monitoring purpose only when all exhaust systems are 'ON'.</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">4.</td><td>Test</td><td>Relief air CFM through relief air filter of HVAC (if applicable)</td></tr>
<tr><td>Acceptance Criteria</td><td>Should be NMT 30%</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">5.</td><td>Test</td><td>Filter Integrity Testing to be done for the Installed filters in the HVAC System.</td></tr>
<tr><td>Acceptance Criteria</td><td>Any leakage should not be more than 0.01% of upstream challenge aerosol concentration.</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">6.</td><td>Test</td><td>Check dust collector / scrubber / point exhaust CFM (If applicable).</td></tr>
<tr><td>Acceptance Criteria</td><td>To be checked at actual</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
</table>

<table>
<tr><td rowspan="3">7.</td><td>Test</td><td>Comprehensive Temperature test and Relative humidity (%) in the area. In case of BMS, corresponding trends to be attached as Annexure.</td></tr>
<tr><td>Acceptance Criteria</td><td>Limit should meet the environmental condition of corresponding unit level SOP.</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">8.</td><td>Test</td><td>Air Differential pressure in the area with respect to adjacent area/ atmosphere (if applicable).</td></tr>
<tr><td>Acceptance Criteria</td><td>Air differential pressure in the area with respect to adjacent area/atmosphere should be within limit and for actual readings refer attached annexure , if applicable.</td></tr>
<tr><td>Observations</td><td>Pass</td></tr>
<tr><td rowspan="3">9.</td><td>Test</td><td>Airflow direction test and visualization</td></tr>
<tr><td>Acceptance Criteria</td><td>The smoke should be diffused uniformly at supply grill/diffusers to room and pass through return grill/diffusers/riser. The smoke should pass from positive area to negative area.</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">10.</td><td>Test</td><td>Particulate matter count ("At rest" condition)</td></tr>
<tr><td>Acceptance Criteria</td><td>No. of particles/m3
Maximum concentration limits
As per EC/WHO/ISO guideline
<table>
<tr><th>Grade / ISO Class</th><th>0.5µ</th><th>5µ</th></tr>
<tr><td>ISO Class 5 / Grade A</td><td>3520</td><td>20</td></tr>
<tr><td>ISO Class 5 / Grade B</td><td>3520</td><td>29</td></tr>
<tr><td>ISO Class 7/ Grade C</td><td>3,52,000</td><td>2900 (As per EC/WHO guideline)
2930 (As per ISO guideline)</td></tr>
<tr><td>ISO Class 8 / Grade D</td><td>35,20,000</td><td>29000 (As per EC/WHO guideline)
29300 (As per ISO guideline)</td></tr>
</table></td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
</table>

<table>
<tr><td rowspan="3">11.</td><td>Test</td><td>Particulate matter count ("In operation" condition)</td></tr>
<tr><td>Acceptance Criteria</td><td>No. of particles/m3
Maximum concentration limits
<table>
<tr><th colspan="3">As per USFDA guideline</th><th colspan="4">As per EC/WHO/ISO guideline</th></tr>
<tr><th>Area Class</th><th>ISO Class</th><th>0.5µ</th><th>Grade</th><th>ISO Class</th><th>0.5µ</th><th>5µ</th></tr>
<tr><td>100</td><td>5</td><td>3520</td><td>A</td><td>5</td><td>3520</td><td>20</td></tr>
<tr><td>10000</td><td>7</td><td>352000</td><td>B</td><td>7</td><td>352000</td><td>2900</td></tr>
<tr><td>100000</td><td>8</td><td>3520000</td><td>C</td><td>8</td><td>3520000</td><td>29000</td></tr>
<tr><td>NA</td><td>NA</td><td>NA</td><td>D</td><td>NA</td><td>Not defined</td><td>Not defined</td></tr>
</table></td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">12.</td><td>Test</td><td>Containment leakage test (if applicable)</td></tr>
<tr><td>Acceptance Criteria</td><td>As per respective SOP</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">13.</td><td>Test</td><td>Area recovery / clean-up period study.</td></tr>
<tr><td>Acceptance Criteria</td><td>As per respective SOP</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">14.</td><td>Test</td><td>Microbial count by settle plate exposure and Air Sampling (If applicable)</td></tr>
<tr><td>Acceptance Criteria</td><td>Should not be more than the limit specified in Microbiological methods (MM) for monitoring environmental control</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
<tr><td rowspan="3">15.</td><td>Equipment Maintenance Details</td><td>All the Planned Preventive Maintenance & Filter Cleaning Activity records to be Reviewed since previous Periodic Performance Verification.</td></tr>
<tr><td>Acceptance Criteria</td><td>All the PPM & Filter Cleaning Activities to be performed & Recorded as per their respective applicable SOP’s.</td></tr>
<tr><td>Observations</td><td>Not applicable</td></tr>
</table>

Note: Microbiological Monitoring is carried out separately as per schedule, Reports or trends to be attached Since last Periodic Performance verification date, (if applicable).

10.0 Frequency:

For Classified area, performance verification study shall be performed once in a year or whenever the changes are incorporated in the area, Equipment or HVAC system.

For Non-Classified areas/General areas, performance verification study shall be performed every Two years or whenever the changes are incorporated in the area, Equipment or HVAC system.

11.0 Deviation/Out of specifications (If any):

NA NA NA

12.0 Review of deviation, change request, and CAPA since last verification:

NA

13.0 Summary of performance verification:

NA

14.0 Recommendation:

NA

15.0 Team Approval :

Department	Approval Remark	Approved By	Approved On
Engineering	ok	Engg User One	12.08.2025 12:37:29
User	NA	No Approval Required	NA
EHS	NA	No Approval Required	NA
Quality Control	NA	No Approval Required	NA
Quality Assurance	NA	No Approval Required	NA

16.0 Review (Inclusive of follow up action, if any):

Approved by Unit Head

17.0 Approved By :

Unit Head One

Unit Head
Date:12.08.2025 12:38:15

18.0 Approved By:

Approved

QA Head One

Head Unit Quality Assurance
Date: 12.08.2025 12:39:54

19.0 Abbreviations:

AHU	:	Air Handling Unit
ACPH	:	Air Changes per Hour
BMS	:	Building Management system
CD	:	Compact Disc
CFM	:	Cubic Feet per Minute
Dept.	:	Department
EC	:	European Commission
EU	:	Eurovent
GMP	:	Good Manufacturing Practice
EHS	:	Environment Health and Safety
HVAC	:	Heating and Air Conditioning System
ISO	:	International Organization for Standardization
m3	:	Cubic meter
mm	:	Millimetre
NA	:	Not Applicable
No.	:	Number
OSD	:	Oral Solid Dosage
SOP	:	Standard Operating Procedure
VFD	:	Variable Frequency Drive
WHO	:	World Health Organization
%	:	Percentage
mu	:	Micron

20.0 References:

ISO 14644	:	Clean rooms and associated controlled environments.
Part - 1	:	Classification of air cleanliness by particle concentration
Part - 2	:	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
Part - 3	:	Metrology and test methods.
Part - 4	:	Design, Construction and Start up.

WHO Technical Report Series No.961, 2011

EC (Brussels, March 2009

"SCHEDULE - M - THE GAZETTE OF INDIA." 2006

1035-G-0045 : Temperature and relative humidity distribution study