



EQUIPMENT QUALIFICATION

Document No.

PERFORMANCE QUALIFICATION

Revision No.

00

Equipment Name

HEATING, VENTILATION AND AIR
CONDITIONING (HVAC) SYSTEM

Page No.

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Equipment Capacity

CFM

PERFORMANCE QUALIFICATION

HEATING, VENTILATION AND AIR CONDITIONING (HVAC)

Document Reference:


Issue Date: _____

Prepared by:

Checked by:

Sign. & Date:

Sign. & Date:

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1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PREPARED BY				
User Department				
REVIEWED BY				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

Prepared by:**Checked by:****Sign. & Date:****Sign. & Date:**

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2.0 OBJECTIVE: To ensure that the installed HVAC system is capable to perform consistently as intended by running the system at operational conditions and recording all relevant operation and results.

3.0 Scope: The scope of this Performance Qualification is for “**HVAC System, Capacity: 1650 CFM,**” which is installed in service area and will supply to Sampling Area -I, Material Airlock and Man Airlock area.

AHU Code: _____

4.0 Reason for PQ:

The reason for preparing this document is:


Please tick any one (or multiple) option(s) from the following (☑):

- New or refurbished premises/equipment
- Purchase of Utility Systems
- Change in Design of Equipment
- In-Use Systems that don't have a URS
- Others (Specify)

5.0 Refer attached Manufacturer/Supplier Performance Qualification No. (if applicable):

Refer attached PQ No.: _____.

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6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the performance qualification protocol and operate/ monitor/ perform the qualification activity and record.
Engineering		To provide support and perform performance qualification.
Health Safety and Environment		To verify and monitor the safety aspects.
Quality Control		To perform the sampling and analysis of samples and provide the results.
Quality Assurance		To be a part of team and review the performance of equipment and documents.
QA Head		To review and approve the Qualification document.
Plant Head		To review and approve the Qualification document.

7.0 Training: Personnel involved in performance qualification activity.

Sr. No.	Name	Training status	Training report availability	Checked by/ date
7.1				
7.2				
7.3				
7.4				
7.5				


Prepared by:	Checked by:
Sign. & Date:	Sign. & Date:

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8.0 Verification of Instruments for Calibration:

Sr. No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by/ Date
8.1					
8.2					
8.3					
8.4					
8.5					
8.6					
8.7					
8.8					
8.9					
8.10					
8.11					
8.12					
8.13					
8.14					
8.15					

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9.0 Performance Check or Challenge Study of the Equipment :

Sr. No.	Methodology/ Description of test	Acceptance criteria	Observation/ Result	Reference Annexure No.	Remarks	Sign / Date
01.	Temperature (Carry out the recording at every two hours interval for total 8 hours for consecutive three working days at operation condition as per SOP No.....)	Limit: NMT 25 °C	Day 1 to 3: Day 1: _____ Day 2: _____ Day 3: _____			
02.	Relative humidity (Carry out the recording at every two hours interval for total 8 hours for consecutive three working days at operation condition as per SOP No. IA/QAD-52)	Limit: NMT 60 %	Day 1 to 3: Day 1: _____ Day 2: _____ Day 3: _____			
03.	Pressure difference in the area with respect to adjacent area. (Record the	From _____ to _____	Day 1: _____ Day 2: _____			

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Sr. No.	Methodology/ Description of test	Acceptance criteria	Observation/ Result	Reference Annexure No.	Remarks	Sign / Date
	observation at every two hours interval for 8 hours for consecutive three working days at operation condition of area as per SOP No. IA/QAD-053)		Day 3: _____			
04.	Particulate matter count (Carry out the test for three consecutive working days at operation condition of area as per SOP No.....)	Should meet the requirement of ISO class 8	Day 1: _____ Day 2: _____ Day 3: _____			
05.	Microbial count: (By Settle Plate Method for three consecutive working days at operation condition of area as per current version SOP No.)	Total viable count: NMT 100 cfu / Plate	Day 1: _____ Day 2: _____ Day 3: _____			

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Sr. No.	Methodology/ Description of test	Acceptance criteria	Observation/ Result	Reference Annexure No.	Remarks	Sign / Date
06.	Microbial count: (By Air Sampling Method for three consecutive working days at operation condition of area as per current version SOP No.	Total viable count: NMT 200 cfu / m ³	Day 1: _____ Day 2: _____ Day 3: _____			

10.0 Performance Check of Software (if any):

Sr. No.	Description of test	Expectation / Acceptance criteria	Result	Pass (Yes / No)	Annexure No.	Remarks	Sign / Date

11.0 Reference Documents: Nil.


Prepared by:	Checked by:
Sign. & Date:	Sign. & Date:

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12.0 Abbreviations: Full forms of all abbreviations are listed here.

<u>Abbreviation</u>	<u>Full form</u>
PQ	: Performance Qualification
No.	: Number
QA	: Quality Assurance
OQ	: Operation Qualification
ID	: Identification
SOP	: Standard operating procedure
OOS	: Out of specification
OOT	: Out of trend
Sr. No.	: Serial Number

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13.0 Attachments: This section contains a list of all attachments referenced in the protocol.

Sr. No.	Attachment Details	Attachment No.
13.1	Temperature and relative humidity monitoring report at Operation condition	Day 1: _____ Day 2: _____ Day 3: _____
13.2	Report of pressure differential reading in the area at Operation condition	Day 1: _____ Day 2: _____ Day 3: _____
13.3	Particulate matter counts report at Operation condition	Day 1: _____ Day 2: _____ Day 3: _____
13.4	Microbial count test by Settle plate method at Operation condition	Day 1: _____ Day 2: _____ Day 3: _____
13.5	Microbial count test by Air sampling method at Operation condition	Day 1: _____ Day 2: _____ Day 3: _____


14.0 Deviations/ Incident/ Changes/ OOS/ OOT (if any):

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Sign. & Date:	Sign. & Date:

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15.0 Recommendations/ Conclusion:

Prepared by:	Checked by:
Sign. & Date:	Sign. & Date:

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16.0 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PERFORMED BY				
User Department				
Engineering				
EHS				
Quality Control (if applicable)				
Validation QA				
REVIEWED BY				
User Dept. Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

Prepared by:	Checked by:
Sign. & Date:	Sign. & Date: