OPERATION QUALIFICATION

HEATING, VENTILATION AND AIR CONDITIONING (HVAC)

Document Reference:

Issue Date: _____

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

CONTENTS

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				

2.0 Objective: To ensure that the installed HVAC system operate according to the approved design, specification and manufacturers operating manual and to record all relevant information and data.

3.0 Scope: The scope of this Operation Qualification is for **"HVAC System, Capacity: 1650 CFM, Make: Crystal"** 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 OQ:

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 Operation Qualification No. (if applicable):

Refer attached OQ No.:_____.

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

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the qualification protocol and verify all the proposed operating parameters of the HVAC System.
Engineering		To verify the key functionalities and parameters
Health Safety and Environment		To verify the safety requirements of HVAC System
Quality Assurance		To be a part of team and review the documents
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

7.0 Training: Personnel involved in qualification activity.

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

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

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					

9.0 Verification of Standard Operating Procedure (SOP) :

Required corrections shall be carried out on draft copy of SOP and SOP shall be finalized.

Sr. No.	SOP Name	SOP No.	Checked by/ Date
9.1	Operation of AHU		
9.2	Filter Cleaning of AHU's / LAF / RLAF, Dynamic Pass Box and Biosafety Cabinet		
9.4	Preventive maintenance of AHU/ Ventilation Unit		

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

Sr. No.	SOP Name	SOP No.	Checked by/ Date
9.5	Operation of Measuring Instruments (Megger, Multi Meter, Lux Meter, Tachometer, Particle Counter, DB Meter, Anemometer, Vibration Tester)		
9.7	Handling, Monitoring, Replacement and Destruction of Filters		
9.9	Recording of temperature and relative humidity		
9.10	Recording of pressure difference		
9.12	Microbiological monitoring of Environment in pharmaceutical area		
9.14	AHU Duct leakage test		
9.15	Measuring the Lux intensity of Light		
9.16	Air pressure differential balancing		
9.17	Clean Room		

10.0 Details of Parameter of DQ Verified in OQ:

Sr. No.	Parameter Mentioned in DQ	Acceptance Criteria (Based on DQ/ Manual)	Observation	Checked by/ Date
12.1	Air change per hour (For one day at Rest condition)	Should be more than NLT 20 air changes per hour for ISO 8 Class area at rest condition.		
12.2	Capacity	1650 CFM		
12.3	HEPA Filter integrity test	Not more than 0.01% of upstream challenge aerosol concentration		
12.4	Particulate matter count: (For one day at Rest condition)	Should meet the specifications of Class / Grade : Class ISO 8 / Grade D area at rest condition.		
12.5	Temperature: (Carry out the recording at every two hours interval for total 8 hours for one day at rest condition)	NMT 25 ºC	Temperature: 1. _____ ^{0}C 2. _____ ^{0}C 3. _____ ^{0}C 4. _____ ^{0}C	
12.6	Relative humidity: (Carry out the recording at every two hours for 8 hours for one day at rest condition)	NMT 60%	Relative Humidity: 1. _____ % 2. _____ % 3. _____ % 4. _____ %	

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Sr. No.	Parameter Mentioned in DQ	Acceptance Criteria (Based on DQ/ Manual)	Observation	Checked by/ Date
12.7	Room pressure w.r.t adjacent room. (Carry out the recording at every two hours for 8 hour for one day)	From _____ to _____	Pressure difference: 1. _____ 2. _____ 3. _____ 4. _____	
12.8	Differential Pressure Across filter bank	It should be within _____ to _____ mm of WC.		
12.9	Air flow pattern test	The Smoke should be diffused uniformly through the supply location and pass through the return location. Smoke should pass from area under positive pressure to area under negative pressure.		
12.10	Area recovery test/ clean up test	Should be achieved within 15 minutes.		
12.11	AHU failure and alarm test	Annunciation/ Alarm system should be generated.		

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Sr. No.	Parameter Mentioned in DQ	Acceptance Criteria (Based on DQ/ Manual)	Observation	Checked by/ Date
12.12	Noise level test	Should be not more than 80 dB in 01 meter distance.		
12.13	Vibration testing	No any abnormal vibration		

13.0 Functional/ Operational Requirements of Equipment:

The desired functional/ operational requirements are listed under this section.

Sr. No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
11.1	Switch `ON' the AHU	Green Indicator shall glow.		
11.2	Switch `OFF' the AHU	Red Indicator shall glow		
11.3	Chilled water inlet Valve	Valve should open in anticlockwise direction and should be closed in clockwise direction. There shall not be any leakage.		
11.4	Chilled water outlet valve	Valve should open in anticlockwise direction and should be closed in clockwise direction. There shall not be any leakage.		

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Sign. & Date:	Sign. & Date

Sr. No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
11.5	Chilled water inlet pressure	Inlet pressure should be about 2.5 kg/cm^2		
11.6	Chilled water inlet temperature	Inlet temperature should be about 8 to 13 ^0C		
11.7	Warm water Inlet valve	Valve should open in anticlockwise direction and should be closed in clockwise direction. There shall not be any leakage.		
11.8	Warm water Outlet valve	Valve should open in anticlockwise direction and should be closed in clockwise direction. There shall not be any leakage.		
11.9	Warm water inlet pressure	Inlet pressure should be About 1.5 kg/cm^2		
11.10	Warm water inlet temperature	Inlet temperature should be about Temperature 30 to 45°C.		
11.11	Switch ON the process air blower.	Process air blower should start		
		Direction of rotation of supply air blower should		

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Sr. No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
		be as specified		
		There should not be any abnormal noise and vibration		
11.12	Operation of Dampers	All dampers Should be closed in clockwise & open in anti-clockwise direction		
11.13	Fresh air quantity	Fresh air quantity should be 10% to 20 % of the total CFM.		

14.0 Reference Documents: Nil.

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

Abbreviation		Full form
DQ	:	Design Qualification
OQ	:	Operation Qualification
SOP	:	Standard operating procedure
Dept.	:	Department
QA	:	Quality Assurance
Sr. No.	:	Serial Number
ID	:	Identification
e.g.	:	Example
&	:	And
RPM	:	Rotation per minute
dB	:	Decibel

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

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

Sr. No.	Attachment Details	Attachment No.

17.0 Deviations/ Changes (if any):

18.0 Recommendations/ Conclusion:

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

19.0 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**