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# INSTALLATION QUALIFICATION

## HEATING, VENTILATION AND AIR CONDITIONING (HVAC)

**Document Reference:**  
**Issue 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
<b>PREPARED BY</b>				
<b>User Department</b>				
<b>REVIEWED BY</b>				
<b>User Dept. Head</b>				
<b>Engineering Dept. Head</b>				
<b>Environment, health and safety</b>				
<b>Quality Control (if applicable)</b>				
<b>Quality Assurance</b>				
<b>APPROVED BY</b>				
<b>QA Head</b>				
<b>Plant Head</b>				

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**2.0 OBJECTIVE:** To ensure that the installed HVAC system conforms to the approved design, specification and manufacturers recommendation.

**3.0 Scope:** The scope of this Installation 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.

Check Point	To be recorded Manually by User	Checked by (Sign/ Date)
Allocated Equipment code		
Installed in Area Name		
PO No. & Date		
Challan / Invoice No.		
Installation Qualification	Start date: _____ End date: _____	

**4.0 Reason for IQ:**

**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 Installation Qualification No. (if applicable):**

Refer attached IQ No.:\_\_\_\_\_.

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**6.0 Responsibility:** Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the qualification protocol and verify all the proposed installation parameters of the HVAC System after/during installation.
Engineering		To verify the utilities, certify components, location and HVAC System parameters
Health Safety and Environment		To verify and provide 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 Equipment Description:**

**Air Handling Unit:**

The air-handling unit serves to condition the air and provide the required air movement within the area.

**Lower plenum:**

The lower plenum shall be fitted on the bottom side of the area.

**Ducting:**

**Supply ducting:** This duct shall be provided between lower plenum and the supply air opening of Air handling unit.

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**Return ducting:** This duct shall be used for conveying the air through return riser to blower section. Then the air shall be circulated through the blower.

**8.0 Environment:** This section gives a brief summary of the layout and physical condition of the proposed site of the HVAC system. This includes (but not limited to), the data sheet of the room where proposed equipment is to be placed with proposed placement drawing showing room dimensions, Design of rooms to be maintained by the HVAC system, drain locations, access route from outside, HVAC supply/return grill locations, utility point locations, etc.

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Available area for installation</b>	4500 mm x 2000 mm x 1200 mm (L x W x H mm)		
2.	<b>Expected size of equipment</b>	Length: 4214 mm Width: 880 mm Height: 950 mm (Maximum)		
3.	<b>Temperature Condition</b>	NMT 25 °C		
4.	<b>Relative Humidity</b>	NMT: 60%		

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**9.0 Functional Requirements of HVAC System:**

**9.1 Installation of the HVAC System:** The desired functional requirements and how it operates are listed under this section.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	<b>Process/ piping instruments diagram.</b>	All instruments and components shall be installed as per drawing.		
2.	<b>AHU unit</b>	Unit shall be installed on rigid fabricated structure and secured in place.  Inspection doors shall be easily accessible.		
3.	<b>Process blower</b>	Alignment of blower and motor shall be done.  Foundation bolts shall be checked for tightness.		
5.	<b>Pre air filter (EU-4)</b>	Installation of filters as per drawing shall be done.  Filters shall be properly installed in the plenum.		
6.	<b>Fine air Filters (EU-7)</b>	Installation of filters as per drawing shall be done.  Filters shall be properly installed in the plenum.		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Manometer should be installed across the filter bank to monitor the filter condition.		
7.	<b>Installation of Filter (EU-13)</b>	Installation of filters as per drawing shall be done.  Filters shall be properly installed in the terminal.  Filters shall be properly secured by tightening the mounting bolt.		
8.	<b>Manometer</b>	Manometer shall be provided across the filter banks as per the drawing.		
9.	<b>Ducting</b>	Supply and return air duct shall be laid as per the approved drawing.  Appropriate gaskets shall be used between the joints.  All ducts shall be supported properly.		
10.	<b>Valves</b>	Two way mixing valve provided for chilled water line.  Isolation valve provided for chilled water line.		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation		Remark
11.	Location Of VFD	Two way mixing valve shall be provided for hot water line.			
		Isolation valve shall be provided for Hot water line.			
		VFD shall be installed near the AHU.			
12.	Identification of HEPA filters installed in the room.	Number of HEPA filters installed in the room.	Area Code	No. of Filters	
			B2-0-003	01 Nos	
			B2-0-004	01 Nos	
			B2-0-005	03 Nos	
13.	Design	Double skin type Outer skin : (CRC powder coated)			
14.	Main motor	Flame proof			
15.	MOC of blower fan	MOC of fan: Mild Steel powder coated			
16.	Process fan detail	Fan RPM : 3433 RPM Fan Type : Backward (PLUG-315) Static pressure: 150 mm Wg Motor HP : 3 HP Motor RPM : 2880			

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Motor type : Foot Mount/ Flame Proof		
17.	Filter Detail	<b>Fresh Air filter:</b> Efficiency: 90% (10 $\mu$ ) Description: EU-4 Type: Flange Frame Material: Alu. Frame		
		<b>Pre filter:</b> Efficiency: 90% (10 $\mu$ ) Description: EU-4 Type: Flange Frame Material: Alu. Frame		
		<b>Fine Filter:</b> Efficiency: 99% (3 $\mu$ ) Description: EU-7 Type: Flange Frame Material: Alu. Frame		
		<b>HEPA Filter:</b> Efficiency: 99.97% (0.3 $\mu$ ) Description: EU-13 Type: Flange Frame Material: Alu. Frame		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Material: Fibre glass media		
		PAO Testing port should be provided for installed HEPA filter leak test and installed HEPA filter should be leak tested at site.		
18.	<b>Electrical motor for main supply blower</b>	Type: 3 Phase induction motor. Motor should be compatible to run with VFD Motor should be Non Flame proof.		
19.	<b>Chilled Water Coil</b>	Face area/ rows: 3.3 Sq.ft. (6rows) Type : Cooling coil Fins Height : 603.25 mm Fins Length : 508 mm Tube size and materials: ½" OD - Copper Fins Material : Aluminium / 12 FPI Header Material: MS		
20.	<b>Hot Water Coil</b>	Face area/ rows: 3.3 Sq.ft. (4rows) Type : Hot water Coil Fins Height : 603.25 mm		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Fins Length : 508 mm Tube size and materials: ½" OD - Copper Fins Material : Aluminium / 12FPI Header Material: MS		
21.	<b>Valve control</b>	Controller and sensor should be provided after coil or in the area for actuation of chilled water control valve.		
22.	<b>Valves and strainers</b>	Isolation valve should be provided at chilled water inlet and outlet.		
		Three way balancing cum control valve for chilled water and three way for hot water should be provided.		
		Strainer should be provided at Chilled water inlet line.		
		Pressure gauge isolation valve should be provided.		
23.	<b>Ducting</b>	<b>a. Return air ducting:</b>		
		Thickness: 24 or 22 Gauge swg. Non soldered.		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Insulation: MOC: Nitrile rubber Thickness : 09 mm		
		<b>b. Supply air ducting</b>		
		Thickness: 24 swg. or 22 swg Non soldered.		
		Insulation: MOC: Nitrile rubber Thickness : 13 mm		
		All duct joints should be filled with sealant for zero leakages.		
		Volume control dampers should be used for the better air control.		
		Neoprene rubber gasket should be used between duct joints.		
		Individual damper for each supply and return of the room side should be provided.		
		Thickness: 24 or 22 Gauge swg. Non soldered.		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
24.	<b>VFD for supply blower</b>	Suitable capacity of VFD to be provided.		
25.	<b>Pipelines</b>	<b>Chilled water lines:</b> MOC: MS C Class heavy duty		
		<b>Insulation:</b> MOC: Nitrile rubber with aluminium cladding.		
		<b>Thickness:</b> 19 mm nitrile with 24 swg. Aluminium.		
		<b>Warm water line:</b> MOC: MS C Class heavy duty		
		<b>Insulation :</b> <b>Thickness :</b> Glass wool with 50mm thick with al. cladding		
	<b>Condensate drain line:</b> MOC : MS C class heavy duty			
26.	<b>Operational feature</b>	AHU should be operational through Auto / Manual switch and also compatible to run with VFD.		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
28.	<b>Fresh air</b>	Minimum 10 - 20%		
29.	<b>Relief air (if applicable)</b>	Not more than 8-10%		
30.	<b>Filter section</b>	All the filter banks, blower section, coil section should have the provision for the measurement of the differential pressure across the filters.		
31.	<b>Damper section</b>	Low leakage aerofoil dampers should be provided.		
		Individual damper should be provided for supply, return, fresh air, relief air, reactivation air etc.		
		All dampers should have positive locking arrangement.		
		<b>Size:</b> Fresh air inlet damper : 100 x 150  Return air damper : 300 x 300  Supply air outlet damper : 300 x 300		

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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Bypass/ Exhaust damper : 250 x 250		

**9.2 Instrumentation Requirements:** This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters. e.g. magnehelic gauge / manometer and etc.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Differential magnehelic gauge / manometer if applicable</b>	Magnehelic manometer should be provided across HEPA / Fine filter bank.		
		Manometer should have proper zero setting.		
		For room : Range 0 to 60 Pascal  For AHU: Range 0 to 25 or 0 to 50 mm of WC		

**9.3 Data Collection and Reporting:** This section mentions in brief the data that is expected from the equipment with the respective unit of measurement. Need for printouts are also mentioned, if applicable e.g. temperature, RPM, pressure, etc.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Temperature</b>	In °C		
2.	<b>Pressure</b>	In MMWC or Pascal (as applicable)		

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**9.4 Performance Features:** The parameters that are planned to be evaluated during performance qualification and validation activities are mentioned.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Performance of the system according to operation.</b>	The system is intended to be operated regularly 24 hours, 7 days per week.		
2.	<b>Cleaning requirements</b>	Easy accessible for cleaning of parts and should be provided with quick fixing arrangement.		

**9.5 Capacity / Speed:** The desired capacity with the UOM is specified in this section.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Capacity</b>	1650 CFM Motor Speed : 2880 RPM		

**9.6 Automation and Safety Features:** The minimum required as well as desired automation and safety features (alarms, interlocking, etc.) are listed in this section.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Noise level</b>	Should be not more than 80 dB in 01 meter distance.		

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Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
2.	<b>Safety guards</b>	Safety guards should be provided to all moving parts.		
3.	<b>Limit switch</b>	Limit Switch should be provided for service door.		
4.	<b>Earthing connections</b>	Proper earthing to be provided.		
5.	<b>View lamp and view window</b>	Wether proof light should be provided in blower section with view glass on panel.		
6.	<b>Smoke detector</b>	Smoke detector should be provided in the service area ceiling (If applicable)		
7.	<b>Alarm system</b>	Alarm should be provided.		
8.	<b>Emergency stop</b>	The system shall have an Emergency stop mechanism.		
9.	<b>Power failure and recovery</b>	The system should not function in case of power failure and starts in auto mode or only after operator intervention.		

9.7 System Boundaries: Nil.

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**9.8 Material of Construction:** Specifications for material of construction of HVAC system parts are listed here.


Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>AHU Frame</b>	Extruded Al Profile(thermal break)		
2.	<b>AHU Panel</b>	Double Skin		
3.	<b>AHU outer skin</b>	0.8 Pre-coated		
4.	<b>Inner Skin</b>	0.6 Plain GI		
5.	<b>Frame work</b>	Aluminium		
6.	<b>Unit Base</b>	G.S.S.		
7.	<b>Process blower</b>	Mild Steel powder coated		
8.	<b>Ducting</b>	Galvanized iron		

**9.9 Surface Finish:** Specifications for surface finish of HVAC system parts are listed here.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Surface of air contact part</b>	There should be no welding burrs.  Surface should be smooth without crevices. All joints should be finished with silicon sealant and there should not be any gap for dust accumulating in the joints.		

**9.10 Electrical and Control Equipment Philosophy:** A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/ microprocessor/

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PLC/ computers or a combination of these are mentioned in this section. The electrical system of the equipment shall be housed as per the cGMP and cGEP.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Operating panel</b>	<ul style="list-style-type: none"> <li>➤ Control ON/OFF button</li> <li>➤ Emergency stop button</li> </ul>		
2.	<b>Control panel</b>	<ul style="list-style-type: none"> <li>➤ All switch gear items are enclosed</li> </ul>		

**10.0 Expected Documents and Drawings:** Requirement of documents (whichever applicable) to be delivered by the manufacturer/ supplier during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

Sr. No.	Document details	Required (✓ / ✗)
1.	Design Specification	✓
2.	Functional Specification	✓
3.	Piping and Instrumentation Diagram (P&ID)	✓
4.	Instrument Listing	✓
5.	Machine Assembly Drawings	✓
6.	Bill of Material	✓
7.	Operator, Maintenance and Service Manual	✓
8.	Spare Parts List	✓
9.	MOC certificates	✓

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Sr. No.	Document details	Required (✓ / ×)
10.	Calibration certificates of instruments	✓
11.	Test certificates of components/test devices	✓
12.	Weld certificates (if any)	✓
13.	'As-built' P&ID	✓
14.	GA drawing	✓
15.	Electrical drawings	✓

✓: Received × : Not Received

**11.0 Available Utilities:**

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Electricity</b>	Electricity: Three phase, 50 Hz.		
		Voltage 240 vac to 415 Volts		
2.	<b>Chilled water</b>	Temperature: 8 to 13°C		
3.	<b>Warm water</b>	Temperature 30 to 45°C		

**12.0 Maintenance Requirements:** Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.

Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
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Prepared by:

Checked by:

Sign. &amp; Date:

Sign. &amp; Date:



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Sr. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	<b>Maintenance requirements</b>	Easy accessible for Maintenance of parts and should be provided with quick fixing arrangement.		
2.	<b>Spare parts</b>	List of Spare parts to be provided.		

**13.0 Reference Documents:** Refer SOP No.: titled as "Qualification of Equipment or Instrument".

**14.0 Abbreviations:** Full forms of all abbreviations are listed here.

**Abbreviation**

**Full form**

- cGMP : Current Good Manufacturing Practice
- CFM : Cubic Feet Per Minute
- dB : Decibel
- EU : European unit
- FLP : Flame proof
- HEPA : High Efficiency Particulate Air
- HVAC : Heating, Ventilation and Air Conditioning
- MOC : Material Of Construction
- MM : Millimeter
- Mm of WC : Millimeter of Water column
- MS : Mild Steel
- NFLP : Non-flame proof
- SWG : Steel wire gauge

<b>Prepared by:</b>	<b>Checked by:</b>
<b>Sign. &amp; Date:</b>	<b>Sign. &amp; Date:</b>







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Sr. No.	Attachment Details	Attachment No.

**17.0 Deviations/ Changes (if any):**

**18.0 Recommendations/ Conclusion :**

<b>Prepared by:</b>	<b>Checked by:</b>
<b>Sign. &amp; Date:</b>	<b>Sign. &amp; Date:</b>



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**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
<b>PERFORMED BY</b>				
User Department				
Engineering				
EHS				
Quality Control (if applicable)				
Validation QA				
<b>REVIEWED BY</b>				
User Dept. Head				
Quality Assurance				

<b>Prepared by:</b>	<b>Checked by:</b>
<b>Sign. &amp; Date:</b>	<b>Sign. &amp; Date:</b>



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<b>APPROVED BY</b>				
<b>QA Head</b>				
<b>Plant Head</b>				

<b>Prepared by:</b>	<b>Checked by:</b>
<b>Sign. &amp; Date:</b>	<b>Sign. &amp; Date:</b>