



	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	1 of 27
Equipment Capacity CFM		


DESIGN QUALIFICATION

HEATING, VENTILATION AND AIR CONDITIONING (HVAC)

Document Reference:

Issue Date: _____


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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	2 of 27
Equipment Capacity CFM		

CONTENTS

S.No.	Title of sections	Page No.
1.0	Pre-Approval	4
2.0	Objective	5
3.0	Scope	5
4.0	Reason for DQ	5
5.0	Refer attached Manufacturer/Supplier Design Qualification No. (if applicable)	5
6.0	Responsibility	6
7.0	Equipment Description	7
8.0	Information of Input Materials	7
9.0	Information of output Materials	7
10.0	Environment	7-8
11.0	Equipment Design and Principle of Working	8
12.0	Process Description	8
13.0	Functional Requirements of HVAC System	9
13.1	Functionality of the HVAC System	9-16
13.2	Instrumentation Requirements:	16
13.3	Data Collection and Reporting	16
14.0	Performance Features	17

Prepared by:	Checked by:
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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	3 of 27
Equipment Capacity CFM		

Continued...

S. No.	Title of sections	Page No.
15.0	Capacity/Speed	17-18
16.0	Automation and Safety Features	19
17.0	System Boundaries	19
18.0	Material of Construction	19
19.0	Surface Finish	19
20.0	Electrical and Control Equipment Philosophy	20
21.0	Expected Documents and Drawings	20-21
22.0	Available Utilities	21
23.0	Maintenance Requirements	21
24.0	Delivery, Installation and Commissioning Requirements	22
25.0	Other Specific Requirements	22
26.0	Reference Documents	22
27.0	Abbreviations	23
28.0	Attachments	24
29.0	Recommendations/ Conclusion	24
30.0	Post approval	25

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



	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	4 of 27
Equipment Capacity CFM		

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				

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	5 of 27
Equipment Capacity CFM		

2.0 OBJECTIVE: To prepare the detailed specification (Design data) for all major components of the HVAC system to ensure that the user requirement specification and Functional requirement specification or data sheet are achieved.

To design the HVAC system in conjunction with the design data in order to provide basis for the vendor, manufacturer the design engineer for designing the system when the project begins.

3.0 Scope: The scope of this Design Qualification is applicable for the procurement of Heating, ventilation and air conditioning system is designed and manufactured according to specified/ required standards and regulation.

4.0 Reason for DQ: To procure Heating, ventilation and air conditioning system for installation in service area and will supply to Sampling Area-I, Material Airlock and Man Airlock area for achieving the required area grade and maintaining the area environmental conditions.

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 Design Qualification No. (if applicable):

Refer attached DQ No.: _____.


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

	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	6 of 27
Equipment Capacity CFM		

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare, evaluate the design parameters with respect to User Requirement Specification (URS), Functional design specification, cGMP requirement and record the information
Engineering		To verify the design, utilities, certify components, location and equipment parameters
Health Safety and Environment		To verify and provide the safety requirements of HVAC and facility
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

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	7 of 27
Equipment Capacity CFM		

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.

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 Information of Input Materials: 10-20% fresh air is taken from service floor and 80-90% of Re-circulated air taken from Sampling Area-I, Material Airlock and Man Airlock area.

9.0 Information of Output Materials: Filtered Air provide to the Sampling Area-I, Material Airlock and Man Airlock area

10.0 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.

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EQUIPMENT QUALIFICATION

Document No.

DESIGN QUALIFICATION

Revision No.

00

Equipment Name

HEATING, VENTILATION AND AIR
CONDITIONING (HVAC) SYSTEM

Page No.

8 of 27

Equipment Capacity

..... CFM


S.No.	Parameter	Acceptance criteria (based on FDS / technical discussion)						Observation	Remark
		Area Name	Length M	Width M	Area M ²	Height M	Volume M ³		
1.	Details of Area to be supplied	Sampling-I	6.85	4.89	33.52	3.00	100.57	20.00	
		M A/L	3.38	2.00	6.76	3.00	20.28	20.00	
		A/L	1.50	2.00	3.00	3.00	9.00	20.00	
2.	Available area for installation	4500 mm x 2000 mm x 1200 mm (L x W x H mm)							
3.	Expected size of equipment	Length: 4214 mm Width: 880 mm Height: 950 mm (Maximum)							
4.	Temperature to be maintained in the area	NMT 25 °C							
5.	Relative Humidity to be maintained in the area	NMT 60 %							

11.0 Equipment Design and Principle of Working:

The unit shall consist of Filter section, Blower section, Heat exchanger section and This unit will be linked with double blower system wherever applicable.

12.0 Process Description: This section mentions in brief the details of the process to be handled by the equipment.

Prepared by:	Checked by:
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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	9 of 27
Equipment Capacity CFM		

- 12.1 The air-handling unit (AHU) will have facility for once through system where 10-20% fresh air is taken from service floor and 80-90% of Re-circulated air for re circulation for Sampling Area-I, Material Airlock and Man Airlock area
- 12.2 The filtered air will be passed through a cooling coil where chilled water is supplied at 8 to 13°C to cool the air to attain the dew point for removal of moisture. The cold air which comes out of the coil will pass through heater coils or warm water coil where the incoming cold air will be heated to maintain the room temperature of NMT 25°C. This air will then pass through a set of filters and dehumidifier before entering the rooms.
- 12.3. Pressure differential across the rooms is designed in a way so as to maintain minimum required pressure differential even when the dust collector is not in operation.

13.0 Functional Requirements of HVAC System:

S.No.	Parameter	Specifications	Observation	Remark
1.	Performance of the system according to operation.	The system is intended to be operated regularly 24 hours, 7 days per week.		
2.	Cleaning requirements	Easy accessible for cleaning of parts and should be provided with quick fixing arrangement.		

13.1 Functionality 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.	Design	Double skinned Outer skin : (CRC powder coated)		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	10 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		CFM : 1650		
2.	Electrical motor for main supply blower	Type: 3 Phase induction motor. Motor should be compatible to run with VFD Motor should be Non Flame proof.		
3.	Process fan detail	Fan RPM : 3433 RPM Fan Type : Backward (PLUG-315) Static pressure: 150 mm Wg Motor HP : 3 HP Motor RPM : 2880 Motor type : Foot Mount/ Flame Proof		
4.	Rates of air changes per hour in cubicle	Should be NLT 20 air changes per hour for ISO class 8 area at rest condition.		
5.	Particulate matter count	Should meet the specifications of Area Class ISO 8 / Grade D.		
6.	Microbial load	Should meet the specifications of Class ISO 8/ Grade D: By Settle plate method: NMT 100 CFU/plate. By Air sampling method: NMT 200		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	11 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		CFU/m ³		
7.	Recovery / Clean up period	Should be achieved within 15 minutes.		
8.	Recovery for temperature and RH	Should be achieved within 30 minutes.		
9.	Air flow pattern	The smoke should be diffused uniformly at supply air location to room and pass through return location. Also smoke should be passed from positive air pressure area to negative air pressure area.		
10.	Filter Detail	Fresh Air filter: Efficiency: 90% (10μ) Description: EU-4 Type: Flange Frame Material: Alu. Frame		
		Pre filter: Efficiency: 90% (10μ) Description: EU-4 Type: Flange Frame Material: Alu. Frame		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	12 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Fine Filter: Efficiency: 99% (3μ) Description: EU-7 Type: Flange Frame Material: Alu. Frame		
		HEPA Filter: Efficiency: 99.97% (0.3 μ) Description: EU-13 Type: Flange Frame Material: Alu. Frame 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.		
11.	Chilled Water Coil	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		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	13 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
12.	Hot Water Coil	Face area/ rows: 3.3 Sq.ft. (4rows) Type : Hot water Coil Fins Height : 603.25 mm Fins Length : 508 mm Tube size and materials: ½" OD - Copper Fins Material : Aluminium / 12FPI Header Material: MS		
13.	Valve control	Controller and sensor should be provided after coil or in the area for actuation of chilled water control valve.		
14.	Valves and strainers	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.		
15.	Ducting	a. Return air ducting:		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	14 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Thickness: 24 or 22 Gauge swg. Non soldered.		
		Insulation: MOC: Nitrile rubber Thickness : 09 mm		
		b. Supply air ducting		
		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.		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	15 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		Non soldered.		
16.	VFD for supply blower	Suitable capacity of VFD to be provided.		
17.	Pipelines	Chilled water lines: MOC: MS C Class heavy duty		
		Insulation: MOC: Nitrile rubber with aluminium cladding.		
		Thickness: 19 mm nitrile with 24 swg. Aluminium.		
		Warm water line: MOC: MS C Class heavy duty		
		Insulation : Thickness : Glass wool with 50mm thick with al. cladding		
		Condensate drain line: MOC : MS C class heavy duty		
18.	Operational feature	AHU should be operational through Auto / Manual switch and also compatible to run with VFD.		
19.	Fresh air	Minimum 10 - 20%		


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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	16 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
20.	Relief air (if applicable)	Not more than 8-10%		
21.	Filter section	All the filter banks, blower section, coil section should have the provision for the measurement of the differential pressure across the filters.		
22.	Damper section	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.		
		Fresh air inlet damper : 100 x 150 Return air damper: 300 x 300 Supply air outlet damper: 300 x 300 Bypass/ Exhaust damper : 250 x 250		

Prepared by:	Checked by:
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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	17 of 27
Equipment Capacity CFM		


13.2 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.

S. No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Differential magnehelic gauge / manometer if applicable	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		

13.3 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.	Temperature	➤ In °C		
2.	Pressure	➤ In MMWC or Pascal (as applicable)		

Prepared by:	Checked by:
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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	18 of 27
Equipment Capacity CFM		

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

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

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

S. No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Capacity	1650 CFM Motor Speed : 2880 RPM		

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

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Noise level	Should be not more than 80 dB in 01 meter distance.		

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Sign. & Date:	Sign. & Date:



	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	19 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
2.	Safety guards	Safety guards should be provided to all moving parts.		
3.	Limit switch	Blower plenum should have limit switch which can switch OFF the blower when plenum door is opened.		
4.	Earthing connections	Proper earthing to be provided.		
5.	View lamp and view window	NFLP view lamp should be provided in blower section with view glass on panel.		
6.	Indicator lamp	Indication lamp for the process air blower, reactivation blower, bed motor, heater bank should be provided (If applicable).		
7.	Smoke detector	Smoke detector should be provided in the service area ceiling (If applicable)		
8.	Alarm system	Alarm should be provided.		
9.	Emergency stop	The system shall have an Emergency stop		

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	20 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		mechanism.		
10.	Power failure and recovery	The equipment should not function in case of power failure and starts in auto mode or only after operator intervention.		

17.0 System Boundaries: Nil.

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

S.No.	Parameter	Specifications	Observation	Remark
1	AHU Frame	Extruded Al Profile(thermal break)		
2	AHU Panel	Double Skin		
3	AHU outer skin	0.8 Pre-coated		
4	Inner Skin	0.6 Plain GI		
5	Frame work	Aluminium		
6	Unit Base	G.S.S.		
7	Process blower	Mild Steel powder coated		
8	Ducting	Galvanized iron		
9	Damper	Aluminium anodized		
10	Chilled water line	Mild steel		

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Sign. & Date:	Sign. & Date:



	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	21 of 27
Equipment Capacity CFM		

S.No.	Parameter	Specifications	Observation	Remark
11	Hot water line	Mild steel		
12	Condensate collector tray	SS-304		
13	Control panel	MS sheet with powder coated/ pre-wired electrical		

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

S.No.	Parameter	Specifications	Observation	Remark
1.	Surface of air contact part	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.		

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

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Operating panel	➤ Control ON/OFF		

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Sign. & Date:	Sign. & Date:




	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	22 of 27
Equipment Capacity CFM		

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
		button ➤ Emergency stop button		
2.	Control panel	➤ All switch gear items are enclosed		

21.0 cGxP Considerations: The requirements for electronic compliance of the HVAC system in case of BMS.

S.No.	Parameter	Specifications
1.	Password protection (if applicable)	Three Level Security should be provided (Operator, Officer and Admin)
2.	Password (if applicable)	Password entries must be obscured (e.g. "*****").
3.	Quality of password (if applicable)	For password at least 4 characters required to enforce their use.
4.	Password protection (if applicable)	Three Level Security should be provided (Operator, Officer and Admin)
5.	Password (if applicable)	Password entries must be obscured (e.g. "*****")
6.	Quality of password (if applicable)	For password at least 4 characters required to enforce their use.
7.	Software (if any)	Software if any shall be 21 CFR part 11 compliance.

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

	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	23 of 27
Equipment Capacity CFM		

22.0 Expected Documents and Drawings: Requirement of documents to be delivered by the suppliers during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

S.No.	Document details	Required (✓ / ✗)
1.	Design Specification	<input checked="" type="checkbox"/>
2.	Functional Specification	<input checked="" type="checkbox"/>
3.	Piping and Instrumentation Diagram (P&ID)	<input checked="" type="checkbox"/>
4.	Instrument Listing	<input checked="" type="checkbox"/>
5.	Machine Assembly Drawings	<input checked="" type="checkbox"/>
6.	Bill of Material	<input checked="" type="checkbox"/>
7.	Operator, Maintenance and Service Manual	<input checked="" type="checkbox"/>
8.	Spare Parts List	<input checked="" type="checkbox"/>
9.	MOC certificates	<input checked="" type="checkbox"/>
10.	Calibration certificates of instruments	<input checked="" type="checkbox"/>
11.	Test certificates of components/test devices	<input checked="" type="checkbox"/>
12.	Weld certificates (if any)	<input checked="" type="checkbox"/>
13.	'As-built' P&ID	<input checked="" type="checkbox"/>
14.	GA drawing	<input checked="" type="checkbox"/>
15.	Electrical drawings	<input checked="" type="checkbox"/>

✓ : Applicable & required ✗ : Not applicable

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Sign. & Date:	Sign. & Date:



	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	24 of 27
Equipment Capacity CFM		

23.0 Available Utilities:

S.No.	Parameter	Specifications	Observation	Remark
1.	Electricity	Electricity: Three phase, 50 Hz.		
		Voltage 240 vac to 415 Volts		
2.	Chilled water	Temperature: 8 to 13°C		
3.	Warm water	Temperature 30 to 45°C		

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

S.No.	Parameter	Specifications	Observation	Remark
1.	Maintenance requirements	Easy accessible for Maintenance of parts and should be provided with quick fixing arrangement.		
2.	Spare parts	List of Spare parts to be provided.		

25.0 Delivery, Installation and Commissioning Requirements:

- 25.1 Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/ supplier service engineer.
- 25.2 Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.
- 25.3 FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

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	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	25 of 27
Equipment Capacity CFM		

25.4 The manufacturer should install, qualify and commission the HVAC System at the user site and provide the necessary training to the user for operation and cleaning. Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of HVAC System.

26.0 **Other Specific Requirements:** To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.

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

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

<u>Abbreviation</u>	<u>Full form</u>
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
ISO	: International Organization for Standardization
MOC	: Material Of Construction
MM	: Microbial Method
Mm of WC	: Millimeter of Water column
MS	: Mild Steel
NFLP	: Non-flame proof
P & ID	: Process and Instrumentation Diagram

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



	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	26 of 27
Equipment Capacity CFM		


- PUF : Poly Urethane Foam
- RH : Relative Humidity
- SWG : Steel wire gauge
- URS : User Requirement Specification
- VFD : Variable Frequency Drive
- "/ cm² : Inch per Centimeter Square
- μ : Micron

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

S.No.	Attachment Details	Attachment No.
1.		
2.		
3.		
4.		
5.		

30.0 Recommendations/ Conclusion:

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

	EQUIPMENT QUALIFICATION	Document No.	
	DESIGN QUALIFICATION	Revision No.	00
Equipment Name	HEATING, VENTILATION AND AIR CONDITIONING (HVAC) SYSTEM	Page No.	27 of 27
Equipment Capacity CFM		

30.0 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: