



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** HEATING, VENTILATION AND AIR  
CONDITIONING (HVAC)

**PROTOCOL No.....**

**FUNCTIONAL AREA:** PRODUCTION

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# USER REQUIREMENT SPECIFICATIONS

**HEATING, VENTILATION AND AIR CONDITIONING (HVAC)**

**Document Reference: Nil**  
**Issue Date: Nil**



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



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**2.0 OBJECTIVE:** The objective of this document is to provide the requirement and appropriate design to support the prospective supplier to identify company needs, price quote for the Heating, ventilation and air conditioning system (HVAC) and performance requirements for procurement of HVAC system including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP.

This URS is an integral part of the procurement agreement with the supplier. The supplier shall abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions of company.

**3.0 Scope:** This user requirement specification (URS) is applicable for the procurement of Heating, ventilation and air conditioning system.

**4.0 Reason for URS:** To procure Heating, ventilation and air conditioning system for installation in service area and will supply to Granulation-1, Material airlock, Airlock and Paste preparation area of Block-1 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)



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

Department	Name	Activity
User		To provide the User Requirement Specification (URS)
Engineering		To provide requirements with respect to utilities, components, based on the location of use and desired HVAC parameters
Health Safety and Environment		To provide the safety requirements of HVAC and facility
Quality Assurance		To be a part of qualification team
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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**6.0 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	Specifications/Dimension																																														
1.	Details of Area to be supplied	<table border="1"> <thead> <tr> <th rowspan="2">AREA NAME</th> <th>LENGTH</th> <th>WIDTH</th> <th>HEIGHT</th> <th>AREA</th> <th>VOLUME</th> <th rowspan="2">ACPH</th> </tr> <tr> <th>M</th> <th>M</th> <th>M</th> <th>M<sup>2</sup></th> <th>M<sup>3</sup></th> </tr> </thead> <tbody> <tr> <td>M A/L</td> <td>3.20</td> <td>3.40</td> <td>3.00</td> <td>10.88</td> <td>32.64</td> <td>10.00</td> </tr> <tr> <td rowspan="2">Granulation-1</td> <td>7.80</td> <td>8.60</td> <td>4.50</td> <td>67.08</td> <td>301.86</td> <td>30.00</td> </tr> <tr> <td>4.20</td> <td>3.30</td> <td>4.50</td> <td>13.86</td> <td>62.37</td> <td>30.00</td> </tr> <tr> <td>A/L</td> <td>3.00</td> <td>1.50</td> <td>3.00</td> <td>4.50</td> <td>13.50</td> <td>10.00</td> </tr> <tr> <td>Paste preparation</td> <td>3.00</td> <td>2.30</td> <td>3.00</td> <td>6.90</td> <td>20.70</td> <td>30.00</td> </tr> </tbody> </table>	AREA NAME	LENGTH	WIDTH	HEIGHT	AREA	VOLUME	ACPH	M	M	M	M <sup>2</sup>	M <sup>3</sup>	M A/L	3.20	3.40	3.00	10.88	32.64	10.00	Granulation-1	7.80	8.60	4.50	67.08	301.86	30.00	4.20	3.30	4.50	13.86	62.37	30.00	A/L	3.00	1.50	3.00	4.50	13.50	10.00	Paste preparation	3.00	2.30	3.00	6.90	20.70	30.00
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Paste preparation	3.00	2.30	3.00	6.90	20.70	30.00																																										
2.	Available area for installation	_____ x _____ x _____ ( L x W x H meter)																																														
3.	Expected size of equipment	Length: 5450 mm Width: 1560 mm Height: 1500 mm (Minimum)																																														
4.	Temperature to be maintained in the area	23 ± 2 °C																																														
5.	Relative Humidity to be maintained in the area	NMT: 60%																																														



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### 7.0 Equipment Design and Principle of Working:

The unit shall consist of Filter section, Blower section, Heat exchanger section and a desiccant re activation type dehumidifier, which will be typically used for low RH application area. This unit shall be linked with double blower system wherever applicable.

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

8.1. The air-handling unit (AHU) shall have facility for once through system where 20% fresh air shall be taken from service floor and 80% of Re-circulated air for re circulation for manufacturing, packaging and storage areas.

8.2. The filtered air shall be passed through a cooling coil where chilled water is supplied at 5 to 8 °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 between 23 ± 2 °C. This air will then pass through a set of filters before entering the rooms. For required RH conditions, dehumidifier of adequate capacity shall be used. Run around coil will recover heat from the return air.

8.3. Dust collectors of adequate capacity are to be provided for areas of high dust generation. The system is designed for high velocity dust collection points with adequate filter provided for capturing the dust. The exhaust from the dust collectors shall be re-circulated to the AHU through EU 13 final filters.

Pressure differential across the rooms shall be designed in a way so as to maintain minimum required pressure differential even when the dust collector is not in operation.

### 9.0 Functional Requirements of HVAC System:

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

Sr. No.	Parameter	Specifications
1.	Design	Double skinned Outer skin : (CRC-powder coated) CFM : 1800 CMH : 3000





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Sr. No.	Parameter	Specifications
2.	Main motor	Flame proof
3.	Process fan detail	Fan capacity : 7650 CFM Fan make : NIKOTRA Fan RPM : 1546 Fan Type : Plug Static pressure : 150 mm WC Motor make : ABB/ Siemens Motor HP : 15 Motor RPM : 1400 Motor type : Foot Mount/ Flame Proof
4.	Reactivation fan detail	Fan capacity : 600 CFM Fan make : LAXMI Fan RPM : 2840 Fan Type : SISW Static pressure : 75 mm WC Motor make : Siemens Motor HP : 1.5 Motor RPM : 2840 Motor type : Flange Mount/ Flame Proof
5.	No. of air changes per hour in cubicle	Should be more than 6 to 20 Nos./ Hour for the Class of area ISO 8 at rest condition.
6.	Particulate matter count	Should meet the specifications of Class / Grade : Class ISO 8 / Grade D area.
7.	Microbial load	Should meet the specifications of Class ISO 8 / Grade D.
8.	Recovery / Clean up period	Should be achieved within 15 minutes.
9.	Recovery for temperature and RH	Should be achieved within 30 minutes.
10.	Air flow pattern	The smoke should be diffused uniformly at supply air location to room and pass through return location.



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Sr. No.	Parameter	Specifications
		Also smoke should be passed from positive pressure area to negative pressure area.
11.	Filter Detail	<p><b>Fresh Air Filter:</b> Efficiency: 90% (10 <math>\mu</math>) Description: Type: Box Frame Material: Alu. Frame Size: H200 x W200 x D50 Material:</p> <p><b>Pre filter:</b> Efficiency: 90% (10 <math>\mu</math>) Description: EU-4 Type: Flange Frame Material: Alu. Frame Size: H610 x W610 x D50 Material: 3 stage NWP sandwiched between 2 layer of HDPE</p> <p><b>Fine Filter:</b> Efficiency: 99% (5 <math>\mu</math>) Description: EU-9 Type: Flange Frame Material: Alu. Frame Size: H610 x W610 x D300 Material:</p> <p><b>HEPA Filter:</b> Efficiency: 99.7% (0.3 <math>\mu</math>) Description: EU-13 Type: Flange Frame Material: Alu. Frame Size: Material:</p>



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Sr. No.	Parameter	Specifications
		<p><b>React. Filter:</b>            Efficiency: 90% (10 μ)            Description:            Type: Box            Frame Material: Alu. Frame            Size: H300 x W450 x D50            Material:</p> <p>PAO Testing port should be provided for installed HEPA filter leak test and installed HEPA filter should be leak tested at site.</p> <p>Access port / Door should be provided to allow HEPA filter integrity test on site.</p>
12.	Electrical motor for main supply blower	<p>Type: 3 Phase induction motor.            Motor should be compatible to run with VFD            Motor should be Flame proof.</p>
13.	Pre Cooling coil	<p>Face area : 1 Sq.ft.            Type : DX/CHW            Cashing : GI - 16/18 SWG            Header : Copper            Tube : Copper            Fins : Aluminium            Fins (FPI) : 12/13 FPI            Drain tray : SS            TR : 2.5            Coil size : 2" OD 305(HT) x 305(LT) x 8 row deep</p>
14.	Post Cooling coil	<p>Face area : 15.5 Sq.ft.            Type : DX/CHW            Cashing : GI - 16/18 SWG            Header : Copper            Tube : Copper            Fins : Aluminium            Fins (FPI) : 12/13 FPI            Drain tray : SS            TR : 16            Coil size : 2 ½" OD 1200(HT) x 1200(LT) x 6 row deep</p>



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Sr. No.	Parameter	Specifications
15.	Hot Water Coil	Face area : 15.5 Sq.ft. Type : HW Cashing : GI - 16/18 SWG Header : Copper Tube : Copper Fins : Aluminium Fins (FPI) : 12/13 FPI Drain tray : SS Line size : 1 1/2" OD Coil size : 1 1/2" OD 1200(HT) x 1200(LT) x 2 row deep
16.	Valve control	Controller and sensor should be provided after coil or in the area for actuation of chilled water control valve.
17.	Valves and strainers	Isolation valve should be provided at chilled water inlet and outlet.
		Two 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.
18.	Ducting	<b>a. Return air ducting:</b>
		Thickness: _____ / _____ swg. Non soldered.
		Insulation: MOC: EPDM rubber Thickness : _____ / _____ mm
		<b>b. Supply air ducting</b>
		Thickness: _____ / _____ swg. Non soldered.
		Insulation: MOC: EPDM rubber Thickness : _____ / _____ mm
		All duct joints should be filled with sealant for zero leakages.
		Volume control dampers should be used for the better air



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Sr. No.	Parameter	Specifications
		control.
		Neoprene rubber gasket should be used between duct joints.
		Velocity sensor port should be provided in supply duct.
		Individual damper for each supply and return of the room side should be provided.
19.	Duct leakages	Should be less than 3 % of total volume handled by system.
20.	VFD for supply blower	Suitable capacity of VFD to be provided.
21.	Pipelines	<b>Chilled water lines:</b> MOC: MS heavy duty
		<b>Insulation:</b> MOC: PUF with aluminium cladding.
		<b>Thickness:</b> _____ mm PUF with _____ swg. Aluminium.
		<b>Warm water line:</b> MOC: MS heavy duty
		<b>Insulation :</b> <b>Thickness :</b> _____ NA _____ mm
		<b>Condensate drain line:</b> MOC : MS heavy duty Size: _____” NB
22.	Operational feature	AHU cum dehumidifier should be operational through Auto / Manual switch and also compatible to run with VFD and BMS.
23.	Fresh air	Minimum 20%
24.	Relief air (if applicable)	Not more than _____%
25.	Filter section	All the filter banks, blower section, coil section should be facilitate with the provision for the measurement of the differential pressure across the filters.



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Sr. No.	Parameter	Specifications
26.	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.
		<b>Size:</b> Fresh air inlet damper : H210 x 210 Return air damper : H400 x 900 Supply air outlet damper : H305 x 305 React air outlet damper : H500 x 500 Bypass damper : H450 x 915
27.	Heater Detail	Heater Quantity : 9 No's.
		Heater type : SS tubular/flame proof
		Capacity each : 4 KW- 3KW
		No. of Heating bank : 2 HB
		Total capacity : 30 KW
28.	Desiccant wheel	Wheel size : 820 x 200

**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	Specifications
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 : _____ to _____ mm of WC For AHU cum dehumidifier : _____ to _____ mm of WC

**10.0 Performance Features:** The parameters that are planned to be evaluated during performance



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qualification and validation activities are mentioned.

Sr. No.	Parameter	Specifications
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.

**11.0 Capacity:** The desired capacity with the UOM is specified in this section.

Sr. No.	Parameter	Specifications
1.	Capacity	1850 CFM Exhaust CFM: 470 Required Fresh air CFM: 470

**12.0 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	Specifications
1.	Noise level	Should be not more than 80 Db in 01 meter distance.
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	FLP / 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 return air duct of AHU (If applicable)



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8.	Fire damper	Fusible link type fire damper shall be provided at the main supply duct. The link should operate at _____°C
9.	Alarm system	Alarm should be provided.
10.	Emergency stop	The system shall have an Emergency stop mechanism.
11.	Power failure and recovery	The equipment should not function in case of power failure and starts only after operator intervention.

**13.0 System Boundaries:** Nil.

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

Sr. No.	Parameter	Specifications
1.	AHU Panel Sheet	Galvanized iron
2.	Process blower	Mild Steel
3.	Ducting	Galvanized iron
4.	Damper	Aluminium
5.	Chilled water line	Mild steel
6.	Hot water line	Mild steel
7.	Condensate collector tray	SS-304
8.	Control panel	GI-with powder coated/ pre-wired electrical

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

Sr. No.	Parameter	Specifications
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.

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





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Sr. No.	Parameter	Specifications
1	Password protection	Three Level Security should be provided (Operator, Officer and Admin)
2	Password	Password entries must be obscured (e.g. "****").
3	Quality of password	For password at least 4 characters required to enforce their use.
4	Parameter report	System Should able to generate parameter reports
5	Viewing of parameter report	System should provide viewing and printing capabilities for all relevant parameter reports
6	Time recording in audit trial	Audit trails should record the hour minute & second of events
7	Time stamps.	The server time should be used for the generation of time stamps.
8	Software Compliance.	Software if any should be 21 CFR part 11 compliance

**17.0 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:

Sr. No.	Document details	Required (✓ / ✗ )
1.	Design Specification	<input type="checkbox"/>
2.	Functional Specification	<input type="checkbox"/>
3.	Alarm/ Interlock/ Safety/ Communication/ Power failure test procedures	<input type="checkbox"/>
4.	Piping and Instrumentation Diagram (P&ID)	<input type="checkbox"/>
5.	Instrument Listing	<input type="checkbox"/>
6.	Control Schematics	<input type="checkbox"/>
7.	Control Panel Assembly Drawings	<input type="checkbox"/>



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Sr. No.	Document details	Required (✓ / ✗)
8.	Machine Assembly Drawings	<input type="checkbox"/>
9.	Bill of Material	<input type="checkbox"/>
10.	Operator, Maintenance and Service Manual	<input type="checkbox"/>
11.	Spare Parts List	<input type="checkbox"/>
12.	MOC certificates	<input type="checkbox"/>
13.	Calibration certificates of instruments	<input type="checkbox"/>
14.	Test certificates of components/test devices	<input type="checkbox"/>
15.	Weld certificates (if any)	<input type="checkbox"/>
16.	'As-built' P&ID	<input type="checkbox"/>
17.	GA drawing	<input type="checkbox"/>
18.	Isometric drawing (if any)	<input type="checkbox"/>
19.	Electrical drawings	<input type="checkbox"/>
20.	Component Cut Sheets (optional)	<input type="checkbox"/>
21.	PLC Program Printouts and Disk File (optional)	<input type="checkbox"/>
22.	HMI Configuration Printout and Disk File (optional)	<input type="checkbox"/>
23.	Other (Specify)	<input type="checkbox"/>

✓: Applicable & required      ✗ : Not applicable

### 18.0 Available Utilities:

Sr. No.	Parameter	Specifications
1.	Electricity	Electricity: Three phase, +N +E, 4 wire
		Voltage _____ to _____ Volts
2.	Chilled water	Temperature 5 to 8°C



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3.	Warm water	Temperature 30 to 40°C
----	------------	------------------------

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

Sr. No.	Parameter	Specifications
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.

**20.0 Delivery, Installation and Commissioning Requirements:**

**20.1** Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/supplier service engineer.

**20.2** Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

**20.3** 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.

**20.4** 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.

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

**22.0 Reference Documents:** Nil.



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**23.0 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	: Euro vent
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
NB	: Nominal Bore
NFLP	: Non-flame proof
PI	: Process and Instrumentation
PUF	: Poly Urethane Foam
RH	: Relative Humidity
SWG	: Steel wire gauge
URS	: User Requirement Specification
VFD	: Variable Frequency Drive
WHO	: World Health Organization
“/ cm <sup>2</sup>	: Inch per Centimeter Square
μ	: Micron
EPDM	: Ethylene Poly Di-Methylene

