User Requirement Specification: Hygienic Air Handling Unit

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1. Objective

This URS defines the performance requirements for **Hygienic HVAC** and will enable the vendor to design, specify, fabricate, install and commission the equipment at SinaDarou Pharmaceutical company.

The Supplier of the HVAC is required to adhere to the content of this document; any deviations proposed must be clearly identified and justified by the Supplier. Compliance with the agreed contents must be a contractual requirement of the purchase order and any costs associated with meeting the agreed requirements must be included in the purchase price

2. Scope

This specification covers the design, assembly, installation, testing and documentation of an air conditioning plant for the ventilation, heating and cooling , including the ducting, the metal structures for supports, the electric power and control cubicles, the electric power and control connections, regulation by programmable logic controllers, and the possibilities for a local monitoring system at SinaDarou Pharmaceutical company.

3. System description

Hygienic air handling units are used in clean rooms, food, medicine and chemistry facilities and in similar places where sensitive sterile conditions are required.
The supplied air is managed by the air handler to control strict room climate conditions, with the ultimate goal of creating an environment promoting higher levels of sanitation while hindering bacteria growth and spread.

4. User Specification

- All materials have to comply with hygiene requirements and be able to prevent the formation of microorganisms.
- All internal surfaces should be perfectly flat
- The system shall have Continuous drainage capability.
- Fans should be able to be cleaned.
- The system shall have Controls that regulate production, transport and storage of each air handling unit, according hygiene requirements.
-The AHU should be clean completely before shipment
- during transportation and storage, the AHU must be sealed in a way that contamination is avoided

5. Mechanical/ Functional/ Process requirement

5.1 Mechanical design

5.1.1 Every section shall have at least one access door or easily removable access panel, to guarantee easy access for cleaning and servicing the components and the casing, unless the section is accessible through another section. The elements of air handling unit shall be accessible upstream or downstream for cleaning purposes, or alternatively they shall be easily and safely removable; this shall be considered when designing the fittings for pipes and ducts. The system consisting of the following as a minimum:

- Dampers
- Filers
- Coil
- Fans
- Droplet separator
- Silencer

- Dehumidifier(optional)

5.1.2 The panels shall be of the “sandwich“ type, consisting of an outer and inner cover with an integrated inner thermal and sound insulation. The covers can be made of galvanized sheet metals with powder coating or of stainless steel.

5.1.3 Smoothness

Any half-closed profiles or joints that can accumulate pollutants and dirt, and are difficult to clean, shall not be accepted, especially in the cabinet floor. All fibrous and porous material, except replaceable components like filter cells, shall be protected by suitable smooth material, which can withstand frequent cleaning. Screws and other similar components shall not protrude from the internal walls.

5.1.4 All units shall be provided with inspection windows and internal lighting for checking at least the fans, filters, humidifiers and cooling coils.

5.1.5 Access door shall be provided as required and detailed under specification of respective components.

5.1.6 The Access doors shall be of the same construction as per the AHU casing and assembled to the profiles by using painted metal hinges.

5.1.7 Access door Gaskets should be inserted, clamped, or foamed. Glued gaskets will not be permitted. Gasket shall have certificate/test report showing proof of microbiological inertness .

5.1.8 Hinged type access door shall be provided with View port or Inspection window. View port or Inspection window and gaskets shall have certificate/test report showing proof of microbiological inertness according to ISO 846 Method A and C

5.1.9 For the necessary IMC works (Inspection, Maintenance and Cleaning), any component (air filters, coils, droplet separators, fans, dampers, silences) in the air stream shall be easily accessible (installed in the AHU) OR alternatively quickly removable.
In any case, sufficient space shall be available in the AHU allowing proper IMC (Inspection, Maintenance and Cleaning).

5.1.10 The supply side shall be filtered by three filter stages. Pre filters (G-4), bag Filters (F-7) and (F-9)

5.1.11 Each filter stage shall be equipped with a differential-pressure gauge (Magnehelic). The measuring display device shall be easily accessible and easily readable by future users.

5.1.12 All the filters shall be non-metallic and non-particle shedding type.

5.1.13 exchangers shall be easy to clean and to disinfect in order to avoid any kind of contamination.

5.1.14 Dampers shall be provided in ducts at every branch supply or return air connection for the proper volume control and balancing of the air distribution system.

5.1.15 System Should have Exhaust and Fresh Damper(With Return Fan)

5.1.16 Inner Casing Surface: Except for doors and hatches grooves, joints and gaps between panels and gaps between panels and frame profiles shall have maximum width of 3mm.

5.1.17 Design Parameters of Filters

5.1.18 all Equipment must be a valid Europen Brand

Parameter	Pre filter	bag filter	bag filter
Grade	(G-4)	(F-7)	(F-9)
Type			
Efficiency	90% down to 10 micron	99% down to 5 micron	99% down to 3 micron
Washable	Yes	Yes	Yes

5.2 Functional design

5.2.1 The HVAC capacity must be 15000CFM.
5.2.2 Heating Coil capacity must be 135-150 KW
5.2.3 Coil capacity must be 250 – 300 kw
5.2.4 Temperature shall be 20 – 25 °C and Humidity ≤ 50%
The installations will be regulated by programmable logic controllers (PLCs).and inveter
T.S.P : 7 IN .H2O
5.2.5 The panel (HMI) must indicate:

- Pressures, temperature, Humidity
- Alarms

5.3 materials

5.3.1 All of the internal sheet metal parts must be stainless steel or Aluminum.
5.3.2 The floor panel must be made of stainless steel.
5.3.3 Metallic material shall be corrosion resistant.
5.3.4 Hygienic HVAC shall have Smooth internal surfaces to prevent adhesion, depositing and release of contaminants.
5.3.5 Non-metalic materials exposed to airstream shall be tested for microbial inertness
5.3.6 Floor and drain pans shall be in stainless steel with at least 18% Cr and 10% Ni (for instance EN steel 1.4401 - AISI 316; minimum corrosion resistance class CRC: II (2) according EN 1993-1-4:1995 EUROCODE 1-4) or aluminum

5.4 LOCATION

5.4.1 The Hygienic HVAC will be located in the eyedrops room in SinaDarou site;
5.4.2 The Hygienic HVAC is located in non-classified room

6. Drawings:

All electrical and mechanical drawings are needed. Any connections between utility system and the HVAC should be clarified in diagrams, Alarms and controls.

Alerts and alarm functions should be specified and cover all system ability to comply with all set points and adjustable parameters.

Parameters and events that should be monitored via calibrated indicators to assure the delivery of the validated process.

7.Testing/Documentation/Training

7.1. Testing

The following qualification stages is required for HVAC system:

- Functional Design Specification (FDS)
- Factory Acceptance Test (FAT)
- Commissioning
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Gassing Cycle Development (GCD)
- Performance Qualification (PQ)

Factory Acceptance Test (FAT) may include but not limited to the following Inspections:

- Dimension and layouts
- Connection size, orientation, position as drawings
- Components and instrumentation as required
- Materials and surface finish to the specification
- documentation (certificates and drawing)
- Alarms and safety tests

7.2 DOCUMENTATION REQUIREMENTS

All documentation must be in English.

Documentation must meet, as a minimum, the following requirements:

- Providing all the details necessary so that the HVAC can be qualified

- Providing ‘as built’ records and drawings.
- Providing information so that operating and maintenance procedures can be prepared.
- Plant items must be uniquely identified on schematic diagrams.
- The final issue by the Supplier of any piece of documentation is to be marked and certified as the “As-built” or “As installed” version. The “As-built” and “As-installed” document is defined as the document which accurately represents the system at Handover, having passed through FAT, DQ, Commissioning, IQ and OQ with all documentation discrepancies cleared and final data verified.

7.2.1 Documentation Pre-Delivery

- Functional Design Specification (FDS), machinery and controls.
- General arrangement drawings and schematics
- Parts list with component specifications
- Material certificates for all product contact parts or certificates of conformity to the specification for all parts not provided with individual material certificates or other quality assurance documents.
  measuring instruments, valves, sensors, etc. (materials must be reliable and reputable European brands)
- Control schematics with control panel layouts and wiring diagrams
- Instrumentation list with calibration certificates for critical instruments
- Operating and Maintenance manuals
- Preventative maintenance schedule and recommended spares list for 2 years
- Executed FAT protocol and qualification protocols for approval
- Commissioning Procedure for comment and approval prior to execution
- Qualification protocols (IQ/OQ/OQ) for approval

7.2.2 Documentation Post-Delivery

- Any documentation which was issued as “preliminary”, “draft” or “for construction” or any other documentation which requires revision as a result of commissioning and qualification must be certified “As Built” and re-issued.
- Executed Commissioning Procedure approved by the Purchaser with a list of commissioning spares replaced.
- Calibration certificates for all test equipment used at any stage.
- Executed qualification protocols and qualification reports for approval

7.3 Training

Training course should be performed by manufacturer on site

References

Appendix H of the ECP-05 AHU for HYGIENIC AIR HANDLING UNITS

VDI 6022 Hygienic aspects for the planning, design, operation and maintenance of air-conditioning systems. 1998

Department	Version
Original version	QA Department
Copy No. 1	QC Department
Copy No. 2	Technical Department