USER REQUIREMENT SPECIFICATION

Name of Item: Air Handling Unit	**Protocol No.**.....
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1.0 **Purpose:** To describe the specific requirement of Heating Ventilation and Air conditioning/AIR HANDLING UNIT System (HVAC) to create a controlled environment for microbiological testing of different materials during routine activities.

2.0 **Scope:** This specification is applicable to the HVAC system to be installed in microbiology laboratory at quality control laboratory.

3.0 **System Description:** The HVAC system to be installed in the microbiology laboratory is required to maintain the clean environment inside the microbiological testing laboratory. The clean environment controls the living particles that would produce undesirable microbial growth. As per different pharmacopoeias the testing of the materials for microbiological contaminations in raw materials and finished products is compulsory. In addition to the microbial limits the testing of specimens for pathogens is also an important test which requires clean room. To attain the required quality of the environment inside the area shall consist of specific features. As per the requirement of international regulatory agencies, the HVAC system shall have the following minimum listed specifications. Before purchasing the equipment additional features shall also be considered.

The HVAC system to generate the clean room environment inside the microbiological laboratory for microbial contamination testing shall have the following listed features.

3.1 The system should be capable to achieve Class 10,000 air quality in the room. The laminar flow installed in the area shall generate class 100 quality of air.

3.2 The system shall be capable of maintaining temperature at 23 ± 2°C with a relative humidity 45% ± 5%. The system should be able to handle lower and higher humidity limits prevailing in the region during extreme humid conditions and low humidity during the hot summer season. Since the personnel working inside the area shall be wearing the full gown, therefore, the temperature inside the room shall be comfortable enough to work inside the area. It should be capable of preventing condensation on the cold surface inside the microbiological area.

3.3 Space pressurization is the key to resistance to infiltration of external sources of contamination; therefore, it should be capable of generating adequate air Pressure Difference (5 to 20 Pa.) in the area. It should be equipped with suitable gauges or indicators to verify the pressure differential.

3.4 Since the HEPA filters are the heart of the HVAC system, therefore, it should be equipped with pre filter units to remove the particulate matter from the air and to prevent damage to the HEPA filters. It should be equipped with HEPA filters located at plenum or terminal for required quality of air.

3.5 A minimum air change rate of 20 per hour should be provided.

3.6 It should be designed in such a way that it does not pollute the outside environment and capable of preventing cross contamination.

3.7 It should have provision to reduce the air turbulence and noise generation during the operation of the system.

3.8 The system should be capable of ensuring about 10% of fresh air intake.

3.9 The entire system shall be energy efficient. The system should be automatic or semi automatic for operation and changeover. Adequate level protection should be there for change of set points. All cold insulation for pipes, ducts shall be vermin proof and non-deteriorating. All rigid foam insulation shall be fire inhibited.

3.10 All electrical & other equipment and gear shall be designed for peak temperature of 50°C and 100% humid conditions. All rigid foam insulation shall be fire inhibited and solvent resistant.

3.11 The system should have the measuring devices of a well known brand and must be calibrated.

3.12 The manufacturer/ supplier should provide complete documentation for validation of the equipment.

3.13 The manufacturer/ supplier should provide the calibration certificates for all the measuring devices including temperature, display units, pressure gauges etc.

3.14 After sales service back up should be from approachable distance so as to minimize breakdown time, if any.

4.0 **Documentation:** Supplier/Manufacturer shall provide the following document.

- P & I diagram, circuit diagrams which ever applicable
- Calibration certificates for all gauges or measuring devices with trace-ability.
- Test and guarantee certificates.
- HEPA filter manufacture certificate.
- HEPA filter installation and validation certificate.
- Qualification (DQ, IQ, OQ, PQ) documentation
- Individual part certificates, if any.

5.0 **Other Considerations:** The manufacture/ supplier shall have the commonly used spares in stock. If not, the manufacture/ supplier shall have the provision to arrange at the earliest. The manufacture/ supplier shall provide the written document for the validation support at the time of placing the final order. The manufacture/ supplier shall provide the general maintenance support to the Engineering section.

Prepared By:
Date:

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Date: