

Specifications Quality Control Sterility/ endotoxin Testing Laboratory

We require design and fabrication of QC sterility lab on Turnkey basis that meets the DRAP requirements and is GMP compliant. Lab should consist of an instrument room, washing area, Sample preparation area, decontamination area (Class C/D) and a Class B area with laminar flow cabinets and Biosafety cabinet to be used for sterility testing and endotoxin testing.

Lab Area Description: Lab total area Length = 9750mm, Width = 7200mm, Frequency of door opening 10-12 times a day, Positive Pressure 5-10 Pa, Temperature 24 deg C with 5% Tolerance, Humidity 50% with 10% Tolerance.

Scope of Work: The bidder shall be responsible for:

~~Turnkey delivery~~, including but not limited to:

Cleanroom construction and finishing

HVAC system (ISO 14644 classified with BMS/EMS)

QC Environmental Monitoring equipment

Validation documentation and execution

Personnel training and handover

S. No	Instrument/ Area	Brief Description	Quantity required
1.	Lab Wall Panels and ceiling	Installation of cleanrooms walls partition panels of galvanized steel sheets, filling of PU, panels thickness 50-100 mm, All required wall panels accessories as per GMP requirements. Installation of cleanrooms ceiling panels of galvanized steel with filling of PU, panels thickness 50-100mm, All required accessories for specific area. Properly sealed, No shedding	As per design requirement
2.	Doors & windows	Installation of Clean room doors with Pu filling and with glass view as per requirement of the lab. Supply and installation of digital door interlocking system between main and internal door of clean room as per clean room international standards. The work may include all the related accessories, controls, cables, gadgets and hardware. Flush, gasketed, interlocked at PAL/MAL. See through windows 3'x3 with double-glazed high-quality glass as per designated wall.	

3.	Epoxy Floor	Prime quality 2-3mm epoxy at flooring of cleanroom. antimicrobial	
4.	Lighting	Installation of high-quality cleanroom lights for whole area according to cleanroom standards. Installation of prime quality power cabling for lights in the entire areas and sockets, plugs and wiring for HVAC equipment and other instruments. The work may include all sizes of cabling, termination etc	
5.	HVAC system	<p>Supply and installation of HVAC equipment including Air Handling Units and Condensing Units / Package Unit. The HVAC equipment will be placed at nearest point of cleanroom including transportation, up-lifting, positioning fixing and installation with gas charging.</p> <p>Cooling Capacity: 35KW</p> <p>Installation of HVAC equipment built in following filters as per cleanroom requirements with allied components, frames and supports:</p> <ol style="list-style-type: none"> 1. G-4 Washable filter 2. Bag Filter F-6, 65% <p>HVAC Equipment DIGITAL THERMOSTAT for HVAC system set point of temperature and allied parameters inside the cleanroom. The Scope includes all control cabling fixing of thermostat, temperature and humidity sensors and allied controls and gadgets with set points complete in all respects.</p> <p>Supply and return air GI ducts and air cladding from HVAC equipment at beside floor level to cleanroom. The ducts may include all fabrication; assembling, and accessories</p>	
6.	Hepa Filters	Supply and installation of HEPA-13 efficiency 99.97% as per ISO standards with complete allied accessories and components. supply griller, hepa housing, return air griller and volume control dampers. Material will be steel painted.	As per design requirement
7.	Insulation	Installation of GLASS WOOL INSULATION with canvas cloth wrapping or aluminum foil with adhesive or with aluminum foil prime quality barrier. The work may include all allied material complete in all respects.	
8.	Air Curtains	Supply and installation of air curtains on main doors of clean	

		room. The vertical flow air curtains must be connected with interlocking system and should be auto operated while main door is opened. The work may include all the related accessories like auto switch, power control cables, hanging material, supports, brackets and hardware to complete the job up to client satisfaction.	
9.	Laminar Flow cabinet	Supply and installation of Laminar Air Flow Cabinets with Hepa filter, UV Lights, blower. The cabinet table must be made of SS-304 material and remaining material should be powder coated ant-static paint. The cabinets must be in good quality with latest aesthetic and as per clean room standards.	03
10.	Bio safety cabinet	Class II	01
11.	Pass boxes	Supply and installation of dynamic pass box for material from non-controlled area to clean room with all its accessories like Hepa filter, blower, standard control and accessories as per clean room standards. The pass box must be window lock system, LED indications indication and all other standard controls.	02
12.	Air particle counter	Particle size 0.3 micron	01
13.	Air velocity Meter	As per requirement of the Clean area instruments	01
14.	Furniture	SS 304/316, Phenolic top, no wood/laminate	As per design requirement
15.	Mandatory Accessories	SS corner guards, SS floor drains, GMP sealants, interlocks, air curtains where applicable, Contact Plate Holder SS, Washing area sinks as per clean area requirements, Storage cabinets etc	As per design requirement
16. 14.	Documentation and Qualification	All required documents and tests for qualification of the lab with DRAP, HEPA integrity test etc	
17.	Warranty	Minimum 1 year, extendable by employer	

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