



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION  
FOR  
REVERSE LAMINAR AIR FLOW**

1.0	Name of Equipment/System	Floor mounted Reverse Laminar Air Flow unit
2.0	Equipment Make/Model	BioKlenz™ Bio-Containment Work Station Model
3.0	Purpose of equipment	For Class 100 / Grade A environment. An ISO Class 5 Type A2 (suitable for Risk Group 2 & 3) Bio-Containment Work Station features inward airflow for personnel protection. The downward HEPA filtered laminar airflow ensures product protection while the HEPA filtered exhaust air takes care of environmental protection.
4.0	Capacity	Inches :                   W x D x H HEPA projected area : 48 x 24 Bioclean Workspace : 48 x 24 x 24 Overall (without duct) :52 x30 x 84
5.0	<b>Process Requirement (s)</b>	<ul style="list-style-type: none"><li>• Airflow pattern is designed for 30% exhaust through HEPA filters to ambient &amp; 70% is recirculated through HEPA filter.</li><li>• The return air plenum is under negative pressure with respect to ambient.</li><li>• <b>CONSTRUCTION: SS304</b> - Filter Frames and motor-blower assemblies in generic execution.</li><li>• SS304 bulkhead.</li><li>• An SS 304 work table, which can be readily removed for cleaning.</li><li>• An SS 304 drain-pan below the perforated portion of the table, with drain faucet.</li><li>• 1-piece fully sliding toughened glass door panel.</li><li>• A 1ft elbow duct for exhaust.</li><li>• <b>REACTIVE FILTERS:</b> All filters are anti-microbial and reactive against bacteria, fungi, viruses and related bio-entities.</li></ul>



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**5.0 Process  
Requirement (s)**

- a. Separatorless Minipleat Anti-microbial UltraKlenz™ HEPA filters of EU 13 grade with an efficiency of 99.97% on mono disperse, 0.3 micron challenge for supply.
  - b. Separatorless Minipleat Anti-microbial UltraKlenz™ HEPA filters of EU 13 grade with an efficiency of 99.99% on mono disperse, 0.3 micron challenge for exhaust.
  - c. *Nouveau* MicroKlenz™ rehabilitable prefilter of EU-6 rating with an efficiency of 60-80% in return path. Media is inherently bactericidal & fungicidal in the return plenum.
- **FEATURES:**
    - a. Custom-built direct drive type motors for supply, with impellers that are statically and dynamically balanced electronically. The machine-made impellers are sized to provide adequate airflow volumes at required total system differential pressures over the full lifecycle of the HEPA filters.
    - b. Enhanced motor-blower execution and unique suspension mounting ensures low vibration, low noise levels. Their dynamic pressure raises all performance parameters, taking those to new benchmarks.
    - c. Remotely located exhaust motor blower.
  - **INSTRUMENTATION AND ACCESSORIES:**
    - a. Sealed white light in excess of 200 LUX in work space.
    - b. Interlocking of supply & exhaust motor blower with logic control to ensure the system stops if either motor stops. This is for additional operator safety.
    - c. Alarm to trigger in case blower trips as a safety measure.



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<p><b>5.0</b></p>	<p><b>Process Requirement (s)</b></p>	<ul style="list-style-type: none"> <li>d. Alarm to trigger in case blower trips as a safety measure.               <ul style="list-style-type: none"> <li>• 0 - 10 mm to indicate negative pressure within the work area with respect to ambient.</li> <li>• 0 - 25 mm to indicate pressure across the supply HEPA filter with respect to ambient.</li> </ul> </li> <li>e. A disinfection port for specific regimens determined by work related bioburden.</li> <li>f. DOP introduction port for upstream challenge of the HEPA filter.</li> <li>g. 5 / 15 Amp single-phase safety socket with switch for external equipment.</li> <li>h. UV light which aids in decontamination of work area.</li> <li>i. Analog hour meter to monitor usage of UV light.</li> <li>• <b>PERFORMANCE</b> <ul style="list-style-type: none"> <li>a. <b>Air cleanliness:</b> ISO Class 5 (ISO 14644-1:1999).</li> <li>b. <b>Air Velocities :</b> 0.45 ± 0.05 mps</li> <li>c. <b>Air Flow :</b> Vertical</li> <li>d. <b>Power Supply :</b> 230 V AC 1-Ø 50Hz</li> </ul> </li> </ul>
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**6.0: Components Details:**

S.No.	Description of Component	MOC/Surface finish	Features
6.1	<b>MOC</b>	<b>SS 304</b>	<ul style="list-style-type: none"> <li>• SS 304 construction</li> </ul>
6.2	<b>Pre filter</b>		<ul style="list-style-type: none"> <li>• As per requirement</li> </ul>
6.3	<b>Intermediate and Final Filter</b>		<ul style="list-style-type: none"> <li>• As per requirement</li> </ul>
6.4	<b>Exhaust filter</b>		<ul style="list-style-type: none"> <li>• As per requirement</li> </ul>



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**7.0: Control Systems:**

**Applicable / Not Applicable**

<b>S.No.</b>	<b>Component(s) / Feature(s)</b>	<b>Required ( Yes/No)</b>	<b>Description (as applicable )</b>
7.1	Power panel - MOC	Yes	SS cover along with magnahelic gauge and ON/OFF switch
7.2	Protection Class	NO	
7.3	Indicator(s)	YES	Magnahelic gauge, motor.
7.4	Alarms and Warnings	YES	Audio visual when motor trips
7.5	Data security	NO	NA
7.6	MMI / HMI and PLC Details	NO	NA
7.7	User interface –compatible to SCADA system.	NO	NA
7.8	Interface to other system (s) / equipment (s) / instrument (s)	NO	NA
7.9	Data storage Capacity	NO	NA
7.10	Password Protection	NO	NA
7.11	Others	Yes	Lighting fluorescent tube with operating switch



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**8.0 Safety features**

**:Applicable / Not Applicable**

<b>S.No.</b>	<b>Safety Feature(s)</b>	<b>Required (Yes/No)</b>	<b>Description (as applicable)</b>
8.1	Emergency Stop	Yes	
8.2	Power Failure / Recovery	No	
8.3	Electrical Protection ( Flame Proof / Non Flame Proof )	Yes	NON FLAME PROOF TYPE
8.4	Alarms & warnings	Yes	MOTOR TRIP ALARM
8.5	Earthing	Yes	
8.6	Noise level	YES	Noise level around the equipment should be Less than 70 db
8.7	Interlocks	NO	
8.8	Others	NO	



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**9.0 Documentation**

**: Applicable / Not Applicable**

S.No.	Title	Required (Yes/No)	Description (as applicable)
9.1	Material of construction Certificate ( MOC ) of Contact Parts / Non contact parts	YES	
9.2	Calibration Certificates traceable to NIST standard	YES	
9.3	Performance Test Certificates	YES	
9.4	Qualification Document (FS /DS / DQ/IQ&OQ document)	YES	
9.5	Operation and Maintenance Manual	YES	
<b>9.6</b>	<b>Drawings</b>		
9.6.1	GA Drawing	YES	
9.6.2	P& ID Drawings	NO	
9.6.3	Electrical	YES	
9.6.4	Ladder Diagram	NO	
9.7	Back up of software / PLC based system	NO	
9.8	Others	NO	



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**10.0: Others**

S.No.	Title	Required (Yes/No)	Description (as applicable)
10.1	Training	-	
10.2	Inspection at Vendor's end	NO	
10.3	Technical support	YES	During Installation at site and validation of the unit
10.4	Others	-	

**11.0: URS Acceptance by the vendor:**

The User requirement specification has been discussed and agreed upon. We hereby declare that we will supply the equipment / system as per above laid down specification.

Name of the Vendor	Signature / Date