USER REQUIREMENT SPECIFICATIONS FOR 3 WAY DYNAMIC PASS BOX

Name of Equipment	**:** 3 way Dynamic Pass Box
Document Number	**:**
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PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR 3 WAY DYNAMIC PASS BOX

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1. PREPARATION & APPROVAL SHEET:

Prepared by

Name	Signature	Date	Department
			Quality Control

Checked by

Name	Signature	Date	Department

Approved by

Name	Signature	Date	Department

2. LIST OF GENERAL COMPONENT:

S.No.	Description
1.	Main Cabinet
2.	Final HEPA Filter
3.	Pre-filter
4.	Fresh Air Filter
5.	Blower and Motor Assemblies
6	Magnehelic Gauge for HEPA filter pressure
7	Atmosphere Nozzle
8	Door release button
9	Electro-magnet Interlocking
10	Power Supply Plug
11	DOP Port
12	ON/OFF Switch
13	UV Light
14	Hour Meter
15	Switch Socket

3. GLOSSARY:

Abbreviation	Description
URS	User requirement specifications
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
Pa	Pascals
HEPA	High Efficiency Particulate Air
SS	Stainless Steel
HP	Horse power
RPM	Rotation Per Minute
MOC	Material of Construction
µ	Micron
EU	Europe Union

4. TECHNICAL:

S.No.	Parameters	Required Specifications
4.1	**General**	
4.1.1	**Description**	This specification is intended to cover the minimum requirements to be met by the vendor in the design, manufacture and supply of 3 way Dynamic Pass Boxes.
4.1.2	**Use**	The Equipment to be used for clean sterile operations to avoid cross contamination of the facility
4.1.3	**Field Identification**	Shall be installed at Microbiology Lab
4.2	**Salient Features**	
4.2.1	**General**	For Class 100 / Grade A environment. An ISO Class 5, Bio-Containment Work Station features inward airflow for personnel protection. The downward HEPA filtered airflow ensures product protection while the HEPA filtered exhaust air takes care of environmental protection.
4.2.2	**Material of Construction**	SS304/SS 316 L
4.2.3	**Finish**	Visually good
4.2.4	**Electrical Construction**	Non flameproof / flameproof.
4.3	**Operational requirements**	Operating requirement based capacity mentioned below:
4.3.1	**Capacity**	(W) 900 mm X (D) 900 mm X (H) 1200 mm
4.3.2	**Control Parameter**	1. Temperature Sensor and humidity sensor shall be installed in return air path. 2. Noise level should not be more than 90dB from 1 meter from the AHU.
4.3.3	**Desired Accuracy**	NA
4.3.4	**Control**	NA
4.3.4.1	**Data & Security**	NA

S.No.	Parameters	Required Specifications
4.3.4.2	**User interface with supervisors and operators for the control platform** **Interface with other Equipment and system**	NA
4.3.4.3	**Security level**	**Motor:** Totally Enclosed, Fan Cooled (TEFC) Squirrel cage induction flame proof motor with IP 55 Protection.
4.3.4.4	**Data collection**	NA
4.3.5	**Component Reference details**	YES
4.3.6	**Functional Requirements**	Functional Requirement of Filters : EU 4 Filter: EU 4 filters having an efficiency of 90 % down to 10 µ. EU 5 Filter: EU-5 Filters having efficiency 95% down 5µ. EU 7 Filter: EU 7Fine filters having an efficiency of 98% down to 3 µ, EU 9 Filter: EU 9 Filters having an efficiency of 98% down to 1 µ. ACROSS FILTER STAGE D.P monitoring require.
4.3.7	**Alarm System**	Preferably the sound alarms/beep shall be provided along with light indication shall be part of BMS.
4.3.8	**Power failure / recovery**	In the event of a power failure, the system shall protect product against damage. The system will stop in a safe mode automatically upon loss of electricity, air or other major utility and will require operator intervention to Restart.
4.3.9	**Emergency stop**	The emergency stop mechanism(s) shall be provided. Fire Damper shall be provide (Fusible Link).
4.4	**Utilities**	Electricity, HVAC Drain, UPS and other utilities shall be discussed as needed.
4.5	**Maintenance**	Supplier should provide the following maintenance instructions, i. Operation and Maintenance manuals along with as built drawings ii. Daily checks on machine Cleaning procedures.
4.6	**Inspection and Testing**	Not Applicable
4.7	**Commissioning and**	• IQ/OQ/PQ to be completed by the supplier along with

S.No.	Parameters	Required Specifications
	Documentation	M/s Panacea representatives. • The Supplier to demonstrate the Performance of the machine at User site as per agreed terms.
4.7.1	**Development**	The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
4.8	**Training**	Supplier to train the respective technical associates of Panacea Biotec Limited on operation, maintenance and cleaning of the equipment wherever applicable.
4.8.1	**Start up support**	Telephone / Fax / E mail ID / Address
4.8.2	**Post start up support**	Replacement parts availability list (normal lead times shall be listed) System improvements (supplier shall notify user of any improvements).
4.9	**Packaging**	Supplier to specify packaging of machine for safe transportation and delivery at the site.
4.10	**Deviations**	Any deviation from URS shall be highlighted.
4.11	**Delivery**	As per Purchase Order.