USER REQUIREMENT SPECIFICATIONS

OF

STERILITY ISOLATOR

List of Contents

PHARMA DEVILS	USER REQUIREMENT SPECIFICATIONS FOR STERILITY ISOLATOR

1. PREPARATION & APPROVAL SHEET:

Prepared by

Name	Signature	Date	Department

Checked by

Name	Signature	Date	Department

Approved by

Name	Signature	Date	Department

2. LIST OF GENERAL COMPONENT:

S.No.	Description
1.	Chamber
2.	Differential pressure monitoring
3.	Blower Motor (FLP)
4.	Frequency inverter
5.	Supply HEPA (Micro fibre glass cartridge)
6	Blower (Centrifugal type)
7	Glove port (PTFE/Circular type)
8	Gloves/Gauntlets
9	Control console
10	RTP (Alpha/Beta Port)
11	Pneumatic cylinders
12	Cleaning Gun (SS)
13	View Panel (AIS)
14	Emergency Stop Button
15	Switch Socket
16.	Light System

3. GLOSSARY

Abbreviation	Description
URS	User requirement specifications
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
PLC	Programmable Logic Control
Pa	Pascals
NPL	National Physical Laboratory
MS	Microsoft
SFU	Switch Fuse Unit
RTD	Resistance Temperature Detector
MOC	Material of Construction
SS	Stainless Steel
MS	Mild Steel
MMI	Man Machine Interface
MM	Millimeter
CM	Centimeter
URS	User requirement specifications
RTD	Resistance Temperature Detectors
FG	Finish Good
API	Active Phamraceutical ingredient
HMI	Human-Machine Interface
VFD	Variable Frequency Drive
MCB	Miniature Circuit Breaker

4. TECHNICAL:

S.No.	Parameters	Required Specifications
4.1	***General***	
4.1.1	**Description**	The Sterility Testing Isolator is a fixed type single chamber, hard wall positive pressure aseptic enclosure suitable to operate thru Six Nos. glove ports integral with a transfer chamber for transfer of necessary sample, media or equipment for one or several tests. Positive pressure interchange allows clean and easy
4.1.2	**Use**	Sterility testing of cytotoxic product
4.1.3	**Field Identification**	Shall be installed at Microbiology Lab
4.2	**Salient Features**	
4.2.1	**General**	(i) Unit to be compact with ease of operation. (ii) A closed system with consistent performance. (iii) Ease of maintenance (iv) Easily cleanable with minimum recesses and crevices. (v) All welded joints to be grinded where product may be in contact to smooth finish and lead free. (vi) All gaskets provided to avoid leakages should be amendable for easy removal and re-fixing, (vii) All electrical / pneumatic parts should be pre wired. (viii) Convenient lubrication design (ix) Complete safety interlock design (x) All bolts, nuts on the exterior part of equipment to be preferably with cap head or cap nut. (xi) Parts which are required for cleaning should be provided with quick fixing arrangement
4.2.2	**Material of Construction**	The isolator chamber is constructed from 3 mm thick, AISI 316 L SS material with 19 mm coving radius. The entire welding is done by TIG welded process, providing a crack free and crevice free smooth inner surface. Service plenum is constructed from 1.6 mm thick AISI 304 SS materials gasketed to the sealed chamber. The differential gauges will be mounted on the service plenum above the chamber. The inner wall of the chamber is polished to Ra <0.6 Micron mirror while the external surface is matt polish (upto Ra <0.70

S.No.	Parameters	Required Specifications
		Micron).
4.2.3	**Finish**	Visually good
4.2.4	**Electrical Construction**	Non flameproof / flameproof.
4.3	**Operational requirements**	
4.3.1	**Capacity**	Work station chamber constructed from AISI 316 L SS and dimension is L 1900 x W 650 x H 800 mm. Chamber shall be suitable for installing closed steritest system (Millipore) having dimensions 280 mm L x 375 mm W x 530 mm H with weight approx. 15 kg in full load condition. ▪ Transfer chamber constructed from AISI 316 L SS and dimension is L 1050 x W 300 x H 800 mm. ▪ Chamber holding platform AISI 304 SS with risers for incoming and exhaust ducts connectivity. ▪ Openable door with compressible gasket made in silicone / EPDM. ▪ Four PTFE glove ports Dia. 250 mm for work station chamber with gauntlets in Hypalon single piece configuration 32" Long) ▪ One PTFE glove ports Dia. 250 mm for transfer box chamber with gauntlet in Hypalon (single piece configuration 32" Long) ▪ Supply and exhaust through HEPA filters. A prefilter is mounted before supply filter to protect the HEPA filter as well as enhance the filtration life. ▪ Supply and exhaust channels are held leak-tight when required by means of leak-proof dampers/valves. ▪ Sterilizable beta 190 mm Dia. with 0.22 micron filters. These beta ports are used for transfer. ▪ Provision for VHP sterilization. ▪ PLC/HMI control onboard to unit. ▪ Pressure, Temperature and Rh monitoring within the chamber. ▪ Velocity monitoring and controls. ▪ Supports and ports for air-born particle sampler and settling plate. ▪ Supports and ports for viable air sampler, PPM testing and TLV testing equipment. ▪ Electrical lighting flush to the inner surface of the chamber. ▪ Glass tempered safety glass 10 mm thk as viewing panel. ▪ Racks / shelves and hanger in SS 316 L material. ▪ The air handling system is onboard (UDAF system). ▪ A Class 100 transfer chamber for product transfer with

S.No.	Parameters	Required Specifications
		HEPA filter and UDAF system. This transfer chamber is designed to maintain +ve pressure and provided with single glove port. ▪ Filter integrity testing ports for all HEPA filters with 100% concentration testing facility.
4.3.2	**The Air Handling System**	The isolator and transfer chamber air handling shall be a UDAF system. The supply air fan is mounted within the service plenum to provide and maintain the unidirectional air flow into the system. The supply filters are aided by UDAF screen provide cover for the work area with unidirectional down flow air that ensures the recommended conditions (ISO 4.8) within the chamber. The inlet is staged with a HEPA (EU-14 Grade) filter. Air is generally recirculated within the chambers through HEPA filters. 10% or 30% exhaust air is exhausted through HEPA filter ending with active carbon filter which acts as catalyst. The exhaust air is controlled by on-line butterfly dampers. The isolator work chamber will be operated at positive pressure +40 Pa (adjustable) with around 40 ACPH and transfer box will operate at positive pressure +60 Pa (adjustable) with larger air changes.
4.3.3	**Air Filtration**	i) Inlet air filter - inlet air pass through a pre-filter followed by (EU-14) cassette type HEPA filter. The efficiency of the HEPA filter is 99.995% MPPS. ii.) Exhaust air passes through exhaust (EU-14) HEPA filters. The efficiency of the HEPA filter is 99.995% MPPS.
4.3.4	**Service Ports**	All service ports shall be made out of AISI 316 SS L with following connectivity :- ▪TC fitting (15 mm NB) for liquid and for gas lines ▪1½" TC with valve for H_2 O_2 entry and exhaust ▪ 6 mm Dia Port for particle counters at the base ▪Port for air sampler ▪ ½" gland to supply the power to steritest assembly
4.3.5	**Mobile Trolley**	Transfer box is provided with a mobile trolley for transferring of material into the work chamber. The mobile trolley is constructed from solid SS 316 L material with perforated shelves for installing load.
4.3.6	**View Panel**	The view panel is glass tempered safety glass, 10 mm thick. The glass vie panel is sealed by static gasket and magnetic locks.

S.No.	Parameters	Required Specifications
4.4	**Gloves and Gauntlets**	Single piece configuration, gauntlet 32" long. Four round glove ports 250 dia. PTFE MOC on chamber. One round glove ports 250 dia. PTFE MOC on transfer box. Gloves in Hypalon (Off white).
4.4.1	**Control Parameter**	The isolator will be having a PLC based control systems. The power panel including PLC, VFD and MCB's etc. will be placed in non-hazardous area. Automation included :
4.4.2	**Desired Accuracy**	▪ Operating pressure + 40 Pa + 10 Pa (work chamber) ▪ Operating pressure transfer box +60 Pa +10 Pa ▪ Temperature at ambient ▪ Preferred Rh control @ 45% and approx. 30% Rh during bio-decontamination ▪ Environmental classification at rest – ISO 5 as per ISO 14644-1 ▪ Leak tightness 0.5% Vol. / hr @ 150 Pa ▪ Power supply 3 KW; 3 phase; 440 V; 50 Hz
4.4.3	**Control**	Manual & Automatic
4.4.4	**Data & Security**	Yes with Password
4.4.5	**User interface with supervisors and operators for the control platform Interface with other Equipment and system**	NA
4.4.6	**Security level**	3 Level Password Protection
4.5	**Data collection**	NA
4.6	**Component Reference details**	YES
4.7	**Alarm System**	Preferably the sound alarms / beep shall be provided The alarm should be on - (a) If chamber leak test is failed. (b) If the chamber temperature overshoots. (c) If humidity level is high (d) If chamber pressure is greater than the set value. (e) If Chamber humidity is high.

S.No.	Parameters	Required Specifications
4.8	**Power failure / recovery**	In the event of a power failure, The system will stop in a safe mode automatically upon loss of electricity, air or other major utility and will require operator intervention to re-start.
4.9	**Emergency stop**	The emergency stop mechanism(s) shall be provided.
4.10	**Utilities**	Supplier to give details and drawings for exact size, location, type, capacity etc. of the utilities required.
4.11	**Maintenance**	Supplier should provide the following maintenance instructions, Operation and Maintenance manuals along with as built drawings Daily checks on machine Cleaning procedures
4.12	**Inspection and Testing**	Not Applicable
4.13	**Commissioning and Documentation**	IQ/OQ/PQ to be completed by the supplier along with representatives. The Supplier to demonstrate the Performance of the machine at User site as per agreed terms.
4.13.1	**Development**	The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
4.14	**Training**	Supplier to train the respective technical associates on operation, maintenance and cleaning of the equipment wherever applicable.
4.14.1	**Start up support**	Telephone / Fax / E mail ID / Address
4.14.2	**Post start up support**	Replacement parts availability list (normal lead times shall be listed) System improvements (supplier shall notify user of any improvements).
4.15	**Packaging**	Supplier to specify packaging of machine for safe transportation and delivery at the site.
4.16	**Deviations**	Any deviation from URS shall be highlighted.
4.17	**Delivery**	As per purchase order.