USER REQUIREMENT SPECIFICATION

FOR

INCUBATION CHAMBER

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PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR INCUBATION CHAMBER

TECHNICAL

S.No.	Parameters	Required Specifications
1.0	***General***	
1.1	**Equipment No.**	NA
1.2	**Description**	Incubation Chamber
1.3	**Use**	Storage of Media Fill Vilas.
1.4	**Field Identification**	Production Area of Oncology Block
1.5	**Glossary**	Attached as Annexure-1
2.0	***Salient Features***	
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.
2.2	**Material of Construction**	SS304/SS 316 L
2.3	**Finish**	Visually good
2.4	**Electrical Construction**	Non flameproof / flameproof.
2.5	**Numbers of tray**	24 nos.
3.0	**Operational requirements**	
3.1	**Capacity**	**Internal Size:** 3000 (W) X 1360 (H) X 3000 (D) mm **External Size:** 3120 (W) X 1480 (H) X 3120 (D) mm
3.2	**Control Parameter**	1. Control temperature accuracy: $\pm$ 2.5 ^{o}C. 2. Temperature uniformity: $\pm$ 1 ^{o}C.

PHARMA DEVILS

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S.No.	Parameters	Required Specifications
3.3	**Working Temperature**	15 °C to 60 °C.
3.4	**Interface with other equipment and system**	Programmed Parameters: fully controlled by programmable logic controller (PLC) and communication on Ethernet.
3.5	**Security level**	3 Level Password Protection
3.6	**Data collection**	Programmable logic controller (PLC) base unit with Ethernet port of communication with software for data acquisition system complying with 21 CFR part 11.
3.7	**Alarm System**	Audio and visual alarms generated for temperature/humidity variation and utility failures. 1. Temperature deviation. 2. Humidity deviation. 3. Utility failure. 4. Emergency alarm for man trap in side Walk-In humidity chamber
3.8	**PLC program details**	**PLC program feature:** 1. Version information. 2. Safety features. 3. Auto change over to stand by system (If present). 4. Manual change over from HMI (If present). 5. Compressor changeover due to HP and LP alarm. 6. PLC IP address setting from HMI. 7. Settable change over time from HMI. 8. Different password protection for set value and calibration mode. 9. Data recording whenever PLC supply is switched ON.
3.9	**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 re-start.
3.10	**Emergency stop**	The emergency stop mechanism(s) shall be provided.
4.0	**Utilities**	Supplier to give details and drawings for exact size, location, type, capacity etc. of the utilities required.
5.0	**Maintenance**	Supplier should provide the following maintenance instructions. • Operation and Maintenance manuals along with as built drawings • Daily checks on machine

S.No.	Parameters	Required Specifications
		• Cleaning procedures
6.0	**Inspection and Testing**	• Traceability of materials certificates indicating lot numbers and other related information. • MOC Certificates, Test/Calibration certificates of all critical and non-critical components.
7.0	**Commissioning and Documentation**	• IQ/OQ to be completed by the supplier along with representatives. • PQ to be completed on 32± 2.5 ° C and 22± 2.5 ° C by the supplier along with representatives.
7.1	**Development**	• The Supplier to demonstrate the Performance of the machine at User site as per agreed terms. • The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
8.0	**Training**	Supplier to train the respective technical associates on operation, maintenance and cleaning of the equipment wherever applicable. Telephone / Fax / E mail ID / Address
8.1	**Start up support**	Replacement parts availability list (normal lead times shall be listed) System improvements (supplier shall notify user of any improvements)
8.2	**Post start up support**	
9.0	**Packaging**	Supplier to specify packaging of machine for safe transportation and delivery at the site.
10.0	**Deviations**	Any deviation from URS shall be highlighted
11.0	**Delivery**	As per purchase order.