



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
COOLING CHAMBERS**

**USER REQUIREMENT SPECIFICATIONS
OF
COOLING CHAMBERS**



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1. PREPARATION & APPROVAL SHEET:

Prepared by

Name	Signature	Date	Department

Checked by

Name	Signature	Date	Department

Approved by

Name	Signature	Date	Department



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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



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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



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4. TECHNICAL:

S.No.	Parameters	Required Specifications
4.1	General	
4.1.1	Equipment No.	NA
4.1.2	Description	Cooling Chambers
4.1.3	Use	Storage of stability Samples.
4.1.4	Field Identification	First Floor of Oncology Block (Quality Control).
4.1.5	Glossary	Attached as Annexure-1
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	SS304/SS 316 L
4.2.3	Finish	Visually good
4.2.4	Electrical Construction	Non flameproof / flameproof.
4.2.5	Numbers of tray	10 nos.
4.3	Operational requirements	
4.3.1	Capacity	Internal Size : 1500 (W) X 1600 (H) X 800 (D) mm External Size : 2095 (W) X 1760 (H) X 1295 (D) mm (2000 Ltrs.)



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S.No.	Parameters	Required Specifications
4.3.2	Control Parameter	<ol style="list-style-type: none"> Control temperature accuracy: $\pm 2^{\circ}\text{C}$. Temperature uniformity: $\pm 1^{\circ}\text{C}$.
4.3.3	Working Temperature	2°C to 8°C.
4.3.4	Interface with other equipment and system	Programmed Parameters: fully controlled by programmable logic controller (PLC) and communication on Ethernet.
4.3.5	Security level	3 Level Password Protection
4.3.6	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.
4.3.7	Alarm System	<p>Audio and visual alarms generated for temperature variation and utility failures.</p> <ol style="list-style-type: none"> Temperature deviation. Door open Utility failure. Emergency alarm for man trap in side Cooling Chamber
4.3.8	PLC program details	<p>PLC program feature :</p> <ol style="list-style-type: none"> Version information. Safety features. Auto change over to stand by system (If present). Manual change over from HMI (If present). Compressor changeover due to HP and LP alarm. PLC IP address setting from HMI. Settable change over time from HMI. Different password protection for set value and calibration mode. Data recording whenever PLC supply is switched ON.
4.3.9	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.
4.3.10	Emergency stop	The emergency stop mechanism(s) shall be provided.
4.4	Utilities	Supplier to give details and drawings for exact size,



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S.No.	Parameters	Required Specifications
		location, type, capacity etc. of the utilities required.
4.5	Maintenance	Supplier should provide the following maintenance instructions. <ul style="list-style-type: none">• Operation and Maintenance manuals along with as built drawings• Daily checks on machine• Cleaning procedures
4.6	Inspection and Testing	<ul style="list-style-type: none">• Traceability of materials certificates indicating lot numbers and other related information.• MOC Certificates, Test/Calibration certificates of all critical and non-critical components.
4.7	Commissioning and Documentation	<ul style="list-style-type: none">• 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.• The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
4.7.1	Development	
4.8	Training	Supplier to train the respective technical associates 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