



**PHARMA DEVILS**

**USER REQUIREMENT SPECIFICATIONS  
FOR  
DEEP FREEZER**

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OF  
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**1. PREPARATION & APPROVAL SHEET:**

**Prepared by**

<b>Name</b>	<b>Signature</b>	<b>Date</b>	<b>Department</b>

**Checked by**

<b>Name</b>	<b>Signature</b>	<b>Date</b>	<b>Department</b>

**Approved by**

<b>Name</b>	<b>Signature</b>	<b>Date</b>	<b>Department</b>



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**2. LIST OF GENERAL COMPONENT**

<b>S.No.</b>	<b>Description</b>
1.	Main Cabinet
2.	Main switch
3.	PLC
4.	Power Supply Plug
5.	ON/OFF Switch
6.	Compressor
7.	Data recorder



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**3. GLOSSARY:**

<b>URS</b>	User requirement specifications
<b>DQ</b>	Design Qualification
<b>IQ</b>	Installation Qualification
<b>OQ</b>	Operational Qualification
<b>PQ</b>	Performance Qualification
<b>°C</b>	Degree Celsius
<b>PLC</b>	Programmable Logic Control
<b>Pa</b>	Pascals
<b>NPL</b>	National Physical Laboratory
<b>O/L</b>	Over Load
<b>SFU</b>	Switch Fuse Unit
<b>RTD</b>	Resistance Temperature Detector
<b>MOC</b>	Material of Construction
<b>SS</b>	Stainless Steel
<b>MS</b>	Mild Steel
<b>KG</b>	Kilogram
<b>MM</b>	Millimeter
<b>CM</b>	Centimeter



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**4. TECHNICAL**

S.No.	Parameters	Required Specifications
<b>4.1.</b>	<b>General</b>	
1.1	<b>Description</b>	Deep Freezer
1.2	<b>Use</b>	Storage of Microbial Culture/ Ref. Standards
1.3	<b>Field Identification</b>	Quality Control Department
<b>4.2.</b>	<b>Salient Features</b>	
4.2.1	<b>General</b>	<ul style="list-style-type: none"><li>(i) Unit to be compact with ease of operation.</li><li>(ii) A closed system with consistent performance.</li><li>(iii) Ease of maintenance</li><li>(iv) Easily cleanable with minimum recesses and crevices.</li><li>(v) All welded joints to be grinded where product may be in contact to smooth finish and lead free.</li><li>(vi) All gaskets provided to avoid leakages should be amendable for easy removal and re-fixing,</li><li>(vii) All electrical / pneumatic parts should be pre wired.</li><li>(viii) Convenient lubrication design</li><li>(ix) Complete safety interlock design</li><li>(x) All bolts, nuts on the exterior part of equipment to be preferably with cap head or cap nut.</li><li>(xi) Parts which are required for cleaning should be provided with quick fixing arrangement.</li></ul>
4.2.2	<b>Material of Construction</b>	SS304/SS 316 L
4.2.3	<b>Finish</b>	Visually good
4.2.4	<b>Electrical Construction</b>	Non flameproof / flameproof.
<b>4.3</b>	<b>Operational requirements</b>	
4.3.1	<b>Capacity</b>	Internal Size : W 600 x D 685 x H 1505 mm External Size : W 720 x D 860 x H 1997 mm
4.3.2	<b>Control Parameter</b>	-10° C to -30° C
4.3.3	<b>Desired Accuracy</b>	<ul style="list-style-type: none"><li>1. Control temperature accuracy: <math>\pm 2^{\circ}</math> C.</li><li>2. Temperature uniformity: <math>\pm 1^{\circ}</math> C.</li></ul>



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S.No.	Parameters	Required Specifications
4.3.4	<b>Control</b>	Microprocessor PID Control with digital LED display
4.3.4.1	<b>Data &amp; Security</b>	Integrated data logger (software included)
4.3.4.2	<b>User interface with supervisors and operators for the control platform Interface with other Equipment and system</b>	Programmed Parameters: fully controlled by programmable logic controller (PLC) and communication on Ethernet.
4.3.4.3	<b>Security level</b>	3 Level Password Protection
4.3.4.4	<b>Data collection</b>	Programmable logic controller (PLC) base unit with Ethernet port of communication with software for data acquisition system complying with 21 CFR part 11.
4.3.5	<b>Component Reference details</b>	YES
4.3.6	<b>Functional Requirements</b>	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. PLC IP address setting from HMI. 6. Different password protection for set value and calibration mode. 7. Data recording whenever PLC supply is switched ON. 8. Auto defrost 9. Heated vacuum valve for frequent door openings
4.3.7	<b>Alarm System</b>	Audio and visual alarms generated for temperature variation and utility failures. 1. Visual & acoustic alarm 2. Utility failure. 3. Auto Door closing & Open Door Alarm 4. Adjustable high/ low Temperature Alarm
4.3.8	<b>Power failure / recovery</b>	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.



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4.3.9	<b>Emergency stop</b>	The emergency stop mechanism(s) shall be provided.
<b>4.4</b>	<b>Utilities</b>	Supplier to give details and drawings for exact size, location, type, capacity etc. of the utilities required.
<b>4.5</b>	<b>Maintenance</b>	Supplier should provide the following maintenance instructions. <ul style="list-style-type: none"> <li>• Operation and Maintenance manuals along with as built drawings</li> <li>• Daily checks on machine Cleaning procedures</li> </ul>
<b>4.6</b>	<b>Inspection and Testing</b>	<ul style="list-style-type: none"> <li>• Traceability of materials certificates indicating lot numbers and other related information. MOC Certificates, Test/Calibration certificates of all critical and non-critical components</li> </ul>
<b>4.7</b>	<b>Commissioning and Documentation</b>	<ul style="list-style-type: none"> <li>• DQ/IQ/OQ/PQ to be completed by the supplier along with representatives.</li> <li>• The Supplier to demonstrate the Performance of the machine at User site as per agreed terms.</li> <li>• Material of construction Certificate (MOC) of Contact Parts / Non-contact parts.</li> <li>• Calibration Certificates traceable to NIST standard.</li> <li>• Performance Test Certificates.</li> <li>• Operation and Maintenance Manual</li> </ul>
4.7.1	<b>Development</b>	The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
<b>4.8</b>	<b>Training</b>	Supplier to train the respective technical associates on operation, maintenance and cleaning of the equipment wherever applicable.
4.8.1	<b>Start up support</b>	Telephone / Fax / E mail ID / Address
4.8.2	<b>Post start up support</b>	Replacement parts availability list (normal lead times shall be listed) System improvements (supplier shall notify user of any improvements)
<b>4.9</b>	<b>Packaging</b>	Supplier to specify packaging of machine for safe transportation and delivery at the site.
<b>4.10</b>	<b>Deviations</b>	Any deviation from URS shall be highlighted