



**PHARMA DEVILS**

**USER REQUIREMENT SPECIFICATIONS  
FOR  
HPHV STEAM STERILIZER**

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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.	Chamber
2.	Jacket
3.	Condenser
4.	Steam Generator
5.	Vacuum Pump
6.	Magnehelic Gauges
7.	Door Open button
8.	Door Close button
9.	Auto Sensor
10.	Power Supply Plug
11.	Printer
12..	ON/OFF Switch
13.	Log data Printer
14.	Emergency Stop Button
15.	Switch Socket



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**3. GLOSSARY:**

<b>Abbreviation</b>	<b>Description</b>
<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>MCB</b>	Miniature Circuit Breaker
<b>PLC</b>	Programmable Logic Control
<b>Pa</b>	Pascals
<b>NPL</b>	National Physical Laboratory
<b>MS</b>	Microsoft
<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>MMI</b>	Man Machine Interface
<b>HPHV</b>	High Pressure and High Vacuum
<b>KG</b>	Kilogram
<b>MM</b>	Millimeter
<b>CM</b>	Centimeter
<b>URS</b>	User requirement specifications
<b>DQ</b>	Design Qualification
<b>IQ</b>	Installation Qualification



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**4. TECHNICAL:**

S.No.	Parameters	Required Specifications
<b>4.1</b>	<b>General</b>	
4.1.1	<b>Description</b>	HPHV Steam Sterilizer with vertical sliding doors.
4.1.2	<b>Use</b>	Sterilization of Media, Glassware, Garments and other accessories used in the microbiological analysis.
4.1.3	<b>Field Identification</b>	Shall be installed at Microbiology Lab.
<b>4.2</b>	<b>Salient Features</b>	
4.2.1	<b>General</b>	(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	<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>	Operating requirement based capacity mentioned below:
4.3.1	<b>Capacity</b>	(W)600mm X (D)900mm X (H)600mm
4.3.2	<b>Control Parameter</b>	Inbuilt electrical control panel and power panel(material SS 304) Working Pressure : Upto 2.2 kg/cm <sup>2</sup> (g). Working Temperature: Upto 134 degree Celsius.
4.3.3	<b>Desired Accuracy</b>	NA



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S.No.	Parameters	Required Specifications
4.3.4	<b>Control</b>	Manual & Automatic
4.3.4.1	<b>Data &amp; Security</b>	Yes with Password
4.3.4.2	<b>User interface with supervisors and operators for the control platform</b>	NA
	<b>Interface with other Equipment and system</b>	3 Level Password Protection
4.3.4.3	<b>Security level</b>	The operator interface (MMI) on to the paneling on the loading side. The Printer on to the paneling on the loading side.
4.3.4.4	<b>Data collection</b>	The strip chart recorder on to the paneling on the loading side.
4.3.5	<b>Component Reference details</b>	YES
4.3.6	<b>Functional Requirements</b>	<u>AUTO MODE:</u> The following process can be performed automatically through PLC: 1. Vacuum Leak Test. 2. Bowie and Dick Test. 3. Standard Process (Gravity Displacement Program). 4. HPHV Process (Pre Vacuum Program with Vacuum Drying). <u>MANUAL MODE:</u> The above-mentioned processes can be performed manually with rocker switch, temperature indicator cum controller and compound gauges.
4.3.7	<b>Alarm System</b>	Preferably the sound alarms / beep shall be provided along with light indication. The alarm should be on if (a) If chamber vacuum leak test is failed. (b) If the chamber temperature overshoots. (c) If chamber temperature falls below specified level & the timer stops counting. (d) If chamber temperature falls further below specified level & the timer resets previously counted time. (e) If chamber pressure is greater than the set value. (f) Too long time for heat up. (g) Too long time for pre vacuum (h) Too long time for post vacuum. (i) If vacuum pump trips. (j) Door pre condition fails.



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S.No.	Parameters	Required Specifications
4.3.8	<b>Power failure / recovery</b>	(k) Compressed Air pressure low. (l) Softened water pressure low. (m) Purified water pressure low.  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.
4.3.9	<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, i. Operation and Maintenance manuals along with as built drawings ii. Daily checks on machine Cleaning procedures
<b>4.6</b>	<b>Inspection and Testing</b>	Not Applicable
<b>4.7</b>	<b>Commissioning and Documentation</b>	<ul style="list-style-type: none"> <li>• 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> </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.
<b>4.11</b>	<b>Delivery</b>	As per purchase order