



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATIONS
FOR
VERTICAL AUTOCLAVE**

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List of Contents

S.No.	Title	Page No.
1.	PREPARATION & APPROVAL SHEET	03
2.	LIST OF GENERAL COMPONENT	04
3.	GLOSSARY	05
4.	TECHNICAL	06
4.1	GENERAL	06
4.2	SALIENT FEATURES	06
4.3	OPERATIONAL REQUIREMENTS	08
4.4	UTILITIES	09
4.5	MAINTENANCE	10
4.6	INSPECTION AND TESTING	10
4.7	COMMISSIONING AND DOCUMENTATION	10
4.8	TRAINING	10
4.9	PACKAGING	10
4.10	DEVIATIONS	10
4.11	DELIVERY	10



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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.	Chamber
2.	Jacket
3.	Condenser
4.	Steam Generator
5.	Magnehelic Gauges
6.	Auto Sensor
7.	Power Supply Plug
8.	Printer
9.	ON/OFF Switch
10.	Log data Printer
11.	Emergency Stop Button
12.	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
°C	Degree Celsius
MCB	Miniature Circuit Breaker
PLC	Programmable Logic Control
Pa	Pascals
NPL	National Physical Laboratory
MS	Microsoft
O/L	Over Load
SFU	Switch Fuse Unit
RTD	Resistance Temperature Detector
MOC	Material of Construction
SS	Stainless Steel
MS	Mild Steel
MMI	Man Machine Interface
HPHV	High Pressure and High Vacuum
KG	Kilogram
MM	Millimeter
CM	Centimeter
URS	User requirement specifications
DQ	Design Qualification
IQ	Installation Qualification



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4. TECHNICAL:

S.No.	Parameters	Required Specifications
4.1	General	
4.1.1	Description	Vertical Autoclave.
4.1.2	Use	Decontamination of media or Sterilization of Media, Glassware, Garments and other accessories used in the microbiological analysis.
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	SS304/SS 316 L
4.2.3	Finish	Visually good
4.2.4	Electrical Construction	Non flameproof / flameproof.
4.3	Operational requirements	Operating requirement based capacity mentioned below:
4.3.1	Capacity	400 (D) X 650 (H) mm



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S.No.	Parameters	Required Specifications
4.3.2	Control Parameter	Inbuilt electrical control panel and power panel(material SS 304) Working Pressure : Up to 1.2 kg/cm ² Working Temperature: 118 to 124 degree Celsius.
4.3.3	Desired Accuracy	NA
4.3.4	Control	Manual & Automatic
4.3.4.1	Data & Security	Yes with Password
4.3.4.2	User interface with supervisors and operators for the control platform Interface with other Equipment and system	NA
4.3.4.3	Security level	3 Level Password Protection
4.3.4.4	Data collection	The Temperature Indicator & Controller fitted Onto the Control Panel. The Timer fitted onto the Control Panel. The Thermograph fitted onto the Control Panel. The circular chart recorder on to the paneling.
4.3.5	Component Reference details	YES
4.3.6	Functional Requirements	Programmed Parameters: Set through Man Machine Interface on control panel.
4.3.7	Alarm System	Preferably the sound alarms / light indication during critical conditions (Emergency). All Safety features shall be provided and should include:- Safety Valves-Chamber Safety Float Switch-Jacket Heater Protection Pressure Switch-Steam Generator Protection Compound Gauges-Chamber Pressure Monitoring
4.3.8	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.



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S.No.	Parameters	Required Specifications
4.3.9	Emergency stop	The emergency stop mechanism(s) shall be provided.
4.4	Utilities	Supplier to give details and drawings for exact size, location, type, capacity etc. of the utilities required.
4.5	Maintenance	Supplier should provide the following maintenance instructions, i. Operation and Maintenance manuals along with as built drawings ii. Daily checks on machine Cleaning procedures
4.6	Inspection and Testing	Not Applicable
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.
4.7.1	Development	The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
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