USER REQUIREMENT SPECIFICATION FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

LOCATION:	**AMPOULE LINE**
SUPERSEDES URS No.	**NIL**

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR HIGH PRESSURE HIGH VACUUM STERILIZER	URS No.:

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1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Equipments, Cleaning Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Steam Sterilizer that meets the user's needs in the most cost-effective method possible.
- The URS to be provided to Vendor to submit a Price Quote for procurement of Steam Sterilizer..
- The URS shall help Vendor in understanding the end user requirement in details. This document shall help vendor for developing the Design Specification, which on approval by the Site will become a Contractual Agreement between vendor and the Site.
- This URS shall be recognized as an integral part of the procurement agreement with the vendor. The vendor will abide by the information and conditions set forth by this document as well as the Standard Purchase Terms and Conditions of the Site.

3.0 SCOPE:

- The Scope of this document is limited to the User Requirement Specification (URS) of high pressure high vacuum steam sterilizer of the Site.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and safety.

4.0 RESPONSIBILITY:

The validation group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, and Approval of User Requirement Specification. • Co-ordination with Production, Engineering and Quality Control to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
Production	• Review of User Requirement Specification for compliance with the Process Requirement.
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP / REGULATORY REQUIREMENTS:

The purpose of Steam Sterilizer is sterilization for Machine Parts & Clean Room Garments.

- Steam Sterilizer shall comply to the "Current Good Manufacturing Practices".
- WHO GMP - "Good Manufacturing Practices for Pharmaceutical Products".
- HTM 2010.
- Schedule –M–"Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."

6.0 SYSTEM OVERVIEW:

- Steam Sterilizer shall be able to sterilize the Machine parts, Accessory & Clean Room Garments with following cycles:
  - Vacuum Leak test
  - Bowie Dick test
  - Standard Process for non porous load
  - High Pressure High Vacuum cycle for Porous load
- Steam Sterilizer shall be equipped with following component:

Door & Door Components

- Double Door system
- Pneumatic Door Operating Cylinder: To Open/Close the Doors.
- Solenoid Valves for Door Operating Cylinder: To operate the door cylinders.
- Pressure Switch: To set the pressure level for the Gasket.
- Pressure Gauges: one on non sterile door side for jacket pressure.
- Vacuum Switch: To set the vacuum level for the Gasket.
- Compound Gauges: Indication of Gasket Pressure.
- FRL: To filter regulate & lubricate the incoming compressed air.
- Regulator: To regulate the incoming compressed air.
- Ejector: To retract the gasket for opening the door.
- Limit Switch: Limit switches to signal the door close position.

Water Recirculatory System:

- Solenoid Valve for Pneumatically Actuated Ball Valve: To operate the rotary actuated ball valves.
- Steam Trap: To prevent steam loss along the condensate removal line.

Process Control:

- Safety Valve : Chamber over pressure protection
- Non return valve : To prevent back pressure in compressed air line
- Compound gauge: Chamber pressure
- Pt-100 Temperature Sensors for temperature monitoring in the chamber
- Vacuum Switch: For air inlet in case of emergency vacuum.

6.1 TECHNICAL SPECIFICATION:

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
1.0	**Chamber**		
	Type	---------	Rectangular
	Chamber internal size	---------	750W x 750H x 1200D
	Chamber Volume	---------	675 L
	MOC	SS 316L	As per CGMP Requirement
2.0	**Jacket**		
	Type	---------	Rectangular
	MOC	SS 304	As per CGMP Requirement
	Type	---------	Rectangular
3.0	**Doors**		
	Type	---------	Double Door, Vertical sliding
	MOC	SS 316	As per CGMP Requirement
	No of doors	--------	02Nos.
	Door insulation	--------	Resin Bonded Glass wool
4.0	**Door gasket**		
	MOC	Food Grade Silicon	As per CGMP Requirement
	Size	--------	As per equipment requirement
	Working temperature	--------	121-134 °C
5.0	**Door operating cylinder**		
	Type of operation	--------	Pneumatic
	Mounting	--------	Vertical
	Door locking cylinder	--------	Horizontal (2 nos.)
6.0	**Insulation**		
	Insulation material	SS 316 L	As per CGMP Requirement
	Outer cover	SS 304 L	As per CGMP Requirement
7.0	**Operating Parameter**		
	Temperature	--------	121-134^{0}C
	Pressure	--------	Approx 1.2-2.1 kg/cm^2
	Vacuum	--------	Full

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
8.0	**Compound Gauge**		
	Range	--------	Range - 1 to 6 To 6 kg/cm2 (g)
	MOC	--------	SS316L for Contact Part SS304 for Non Contact Part
	NO.	--------	02
9.0	**Validation Port**		
	MOC	SS316	As per CGMP Requirement
	NO.	--------	2 Nos.
	NO of sensor arrangement		No of sensor arrangement in each port: 8
10.0	**Port for RTD Sensor**		
	MOC	SS316	As per CGMP Requirement
	NO.	--------	1 No
	NO of sensor arrangement	--------	No of sensor arrangement in each port: 8
11.0	**Switches**		
	Pressure switch	--------	02 Nos.
	Vacuum switch	--------	02 Nos.
	Photo cell sensor	--------	2 No. for door obstruction safety
12.0	**Control Panel On Loading Side**		
	Push button	--------	Color push button for – • Loading door open & close • Emergency stop
	Indication lamp	--------	Door pre condition
			Alarm indication
	Strip chart recorder	--------	Strip chart recorder on loading side
	MMI	--------	Onto the control panel
13.0	**Control Panel On Unloading Side**		
	Push button	--------	Color push button for – • Loading door open & close • Emergency stop • Door open acknowledge
	Indication lamp	--------	Door pre condition
			Process on/end condition
14.0	**Safety**		

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
	Door inter lock	--------	Both the door should not opened simultaneously
	Door obstruction	--------	Door shall be obstructed by hand
15.0	Temperature sensor (Inside the chamber)	Pt 100	Make - radix Accuracy - Class A Qty – 04 Nos. Range – Approx
16.0	Air filter	--------	0.2 micron
17.0	Temperature indicator controller	--------	Range – 0 to 200 ° C Make – Radix Qty -01 No.
18.0	Extension card	--------	As per your specification
19.0	Printer	--------	Dot matrix Online printer
20.0	**Accessories**		
	Trolley	SS 304	As per your design
	Carriage	SS 316	With perforated shelves

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7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 LAY OUT:

- Should accommodate Size of equipments, utility services to be provided, Operating space and clearance for maintenance activity.
- Should be suitable such that after placement of equipments in the area the scope for personal movement and maintenance activity is not disturbed.

7.2 FUNCTIONAL REQUIREMENTS:

- The system shall comply with cGMP.
  Steam Sterilizer shall comply with the “Current Good Manufacturing Practices”.

7.3 UTILITY REQUIREMENTS:

- System shall accept Ampoule line 415 ± 10% V supplies.
- Pure Steam Gas Inlet

7.4 SAFETY REQUIREMENTS:

- Emergency push button shall be provided.
- Electric panels shall not have any unsecured joints.
- Double earthing shall be provided for all electrically operated equipments.
- Noise pollution shall be kept below 80 db.
- Safety valves to Protect chamber & Jacket from over pressure.
- Insulation to Jacket to prevent opening of Door under pressure.
- Pressure Switches to protect chamber & Jacket from over pressure.

7.5 MAINTENANCE:

- The Equipment shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- The supplier shall provide all spare parts at the production site before the start of Steam Sterilizer.
- The supplier shall replace the parts found to be damaged/ broken during installation.
- The supplier shall be available at the site when asked in case of major breakdown.

8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

- The supplier shall follow cGMP practices in design, development, construction and Installation of the system.

8.2 TESTING:

- The system shall be Factory tested by the supplier with approval witness.
- The system shall be commissioned and qualified at site for Installation and Operation by the supplier with approval witness.

8.3 SUPPORT

- Supplier shall provide support for Preventive maintenance plan development, Operator training, Cleaning of the equipment etc.

8.4 DELIVERY

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification and other qualification documents (DQ, IQ & OQ) in soft copy.

9.0 DOCUMENTS TO BE ATTACHED:

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer’s calibration certificate.
- Electrical unit Diagram.
- P&ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine
- Test Certificate of SS Materials

10.0 REVIEW/COMMENTS:

- The supplier should make/design the HPHV as per technical specification mentioned in the URS.
- For any changes in the design/make of the HPHV, if not as per the URS, prior intimation/approval should be taken by the supplier from the Site.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Approved By
Head -QA
Sign/Date :……..

11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practices
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization