



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
LEAK TESTING CUM TERMINAL STERILIZER**

URS No.:

**USER REQUIREMENT
SPECIFICATION
FOR
LEAK TESTING CUM TERMINAL
STERILIZER**

LOCATION	AMPOULE LINE
SUPERSEDES URS No.	NIL



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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)			



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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 Instruments, Cleaning / Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional **Leak Testing Cum Terminal Sterilizer** that meets the user's needs in the most cost-effective method possible.
- The URS is then provided to Vendor to submit a Price Quote for procurement of Leak Testing Cum Terminal 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 Leak Testing Cum Terminal 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.



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4.0 RESPONSIBILITY:

The Team, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation and Approval of User Requirement Specification.• Co-ordination with User Department to prepare User Requirement Specification.• To check the completeness and Technical Accuracy of the URS.
User Department	<ul style="list-style-type: none">• Review of User Requirement Specification for compliance with the Product Requirement.

5.0 GMP/REGULATORY REQUIREMENTS:

- The Purpose of procuring Leak Testing Cum Terminal Sterilizer is Used to sterilize the Accessory, Clean Room Garments, Ampoule leak test, Ampoule Washing & rapid cooling process .
- **Leak Testing Cum Terminal Sterilizer** should complies with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.



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6.0 SYSTEM OVERVIEW:

- Leak testing cum terminal Sterilizer shall be able to sterilize the Accessory , Clean Room Garments , Ampoule leak test ,Ampoule Washing & rapid cooling process with following cycles:
 - Vacuum Leak test
 - Bowie Dick test
 - Standard cycle
 - HPHV cycle
 - Rapid cooling cycle
 - Ampoule leak test
 - Ampoule washing cycle
- **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.



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6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.	Equipment Name	---	Leak Testing Cum Terminal Sterilizer with PLC.
2.	Modal /Type	---	Should be in compliance with cGMP.
3.	CHAMBER		
	Internal Size		As per Purchase order.
	Plate Thickness		6 mm
	All contact parts	SS316L	As per cGMP Requirements
	Non contact parts	SS304	
	Finish	---	$Ra \leq 1.0$
	Design Code	---	ASME SEC VIII DIV – 1
	Welding Joint Radiography	---	10% of Weld Length
4.	JACKET		
	Type	---	Full
	Plate Thickness	---	5 mm
	Material	---	SS304
5.	AIR POCKET		
	Plate Thickness	SS304	5 mm
6.	SHELL INSULATION		
	Insulation Material	---	Resin Bonded Glass wool
	Insulation Thickness	---	50 mm
	Insulation Skin Temperature (Average)	---	35 ⁰ C above Ambient Temperature
	Insulation Cover Material	---	SS304
	Insulation Cover Thickness	---	0.63 mm
	Insulation Cover finish	---	$Ra \leq 1.0$
7.	STAND		



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S.No.	Name of the Component	MOC	Technical Specification
	Stand material(MOC)	---	SS304
8.	SKID		
	Material	---	SS304
9.	RAILS & BAFFLES		
	Rail Pipe Materials	---	SS316
	Steam Baffle Material	---	SS316
10.	GAUGES		
	Pressure Gauge		
	Mounting	---	Panel
	Range	---	0 to 6 kg/cm ²
	Connection	---	3/8" BSP, back connection
	Qty.	---	01 No
	Function	---	Indication of jacket pressure
	Location	---	Non sterile Side
11.	Compound Gauge		
	Mounting	---	Panel
	Range	---	-1 To 6 kg/cm ²
	Qty.	---	02 Nos (on St side & Nst side)
	Connection	---	3/8" BSP, back connection
	Location	---	Sterile & Non Sterile side
	Function	---	Indication of chamber pressure
12.	Validation Port with Dummy Adaptor		
	No of sensor arrangement in each port	SS316	08 Nos.
	Qty.	---	02 Nos.
13.	Port for Chamber Flexible RTD Sensor		
	MOC	SS316	As per cGMP Requirements
	No of sensor arrangement in port	---	08 Nos.
	Qty.	---	02 No.



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URS No.:

S.No.	Name of the Component	MOC	Technical Specification
14.	DOOR		
	Type	---	Horizontal Sliding
	Quantity	---	Two
	Material	SS316L	for Contact Part
	Finish	--	Ra ≤ 0.8
15.	DOOR INSULATION SYSTEM		
	Insulation Material	---	Resin Bonded Glass wool
	Insulation Thickness	---	75 mm
	Insulation Outer Cover Material	SS304	As per cGMP Requirements
	Insulation Outer Cover Material Thickness	---	1.25 mm
16.	DOOR COMPONENTS		
	Door Component Material	SS304	As per cGMP Requirements
	Door Extension Material	SS304	As per cGMP Requirements
17.	DOOR GASKET		
	Material	---	Food Grade Silicon
	Size	---	As per your specification
	Working Temperature	---	134 ⁰ C
	Working Pressure	---	3 kg/cm ² (g)
	Qty	---	2 Nos
	Function	---	To seal gap between chamber & door
18.	PNEUMATIC DOOR OPERATING CYLINDER		
	Mountaing	---	Horizontal
	Qty	---	02 Nos
	Size	---	To suit the process requirements
	Function	---	To open & close the door
19.	SOLENOID VALVES FOR DOOR OPERATING CYLINDER		
	Pneumatic Pressure Range	---	5-6 kg/cm ²
	Coil Supply	---	1ph-230V-50 hz



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URS No.:

S.No.	Name of the Component	MOC	Technical Specification
	Qty	---	02 Nos
	Function	---	To operate the door operating cylinder
20.	SOLENOID VALVES FOR GASKET PRESSURISATION /RETRACTION		
	Model	---	2 Way On/Off
	Coil Supply	---	1PH – 230V – 50Hz
	Qty	---	5 Nos
	Function	---	To pressurize and retract the gasket to facilitate the door opening and closing
21.	PRESSURE SWITCH		
	Model	---	NMG H04 CS10
	Qty	---	02 Nos.
	Function	---	To set the pressure level for the gasket on the sterile side and non sterile Side.
22.	VACUUM SWITCH		
	Model	---	NMG V00 CS10
	Qty	---	02 Nos.
	Function	---	To set the Vacuum level for the gasket on sterile side and Non sterile side.
23.	LIMIT SWITCH		
	Model	---	1 NO+1Nc
	Qty	---	08 Nos.
	Function	---	4 switches used for sensing the door position. 4 switches are located on the door for door obstruction safety
24.	FILTER LUBRICATOR REGULATOR		
	Size	---	¼” BSP
	Range	---	0 to 10 kg/cm ²
	Function	---	To filter, regulate & lubricate the incoming compressed air.
25.	REGULATOR		
	Size	---	¼” BSP
	Range	---	0 to 10 kg/cm ²



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S.No.	Name of the Component	MOC	Technical Specification
	Function	---	To regulate incoming compressed air
26.	EJECTOR		
	Size	---	1/4" BSP
	Function	---	To retract door gasket before opening door.
27.	CONTROL INDICATION ON UNLOADING SIDE		
	Push Buttons with indication lamps	---	Colour coded push buttons with indication lamps 1. Unloading door open. 2. Unloading door close. 3. Unloading door acknowledge. 4. Emergency stop.
	Indication lamps	---	Colour coded indication lamps 1. Door precondition indication. 2. Alarm Indication.
28.	CONTROL INDICATION ON LOADING SIDE		
	Push Buttons with indication lamps	---	Colour coded push buttons with indication lamps: 1. Loading door open. 2. Loading door close. 3. Emergency stop. 4. Control on/off switch. 5. Heater on/off switch.
	Indication lamps	---	Colour coded indication lamps. 1. Door precondition indication. 2. Alarm Indication.
29.	VACUUM SYSTEM		
	Vacuum Pump & Motor	---	
	Type	---	Watering Type
	Capacity	---	120 CU.M /HR
	Location	---	On Stand
	Motor	---	LHP
	HP/RPM	---	7.5 HP / 2850 RPM
	Function	---	To create the vacuum in the chamber



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URS No.:

S.No.	Name of the Component	MOC	Technical Specification		
30.	STEAM CONDENSER				
	Type	SS304	Shell & Tube		
	Transfer area	---	0.24 m ²		
	Function	---	To condense the exhaust steam (from chamber) before entering the vacuum pump.		
31.	PNEUMATICALLY ACTUATED BALL VALVE				
	Model	---	Single acting		
	End connection	---	BSP/ Triclover		
		---	Valve No.	Size	Function
		---	202	1 ½" OD TC	Chamber Vacuum
		---	208	½" OD TC	Chamber filter air in
	---	301	¾" BSP	Cooling water into vacuum Pump	
32.	NON RETURN VALVE FOR VACUUM PUMP DRAIN & VACUUM PIPELINE				
	Size	---	½"BSP ,1 1/2 BSP		
	MOC	---	Brass		
	Qty.	---	1 No Each		
	Function	---	To prevent back pressure from the drain line to the chamber		
33.	AIR BREAK FILTER				
	Retention	---	0.02 micron		
	Size	---	½" BSP		
34.	VACUUM BREAKER				
	Model	---	½" BSP		
	MOC	---	SS304		
	Qty.	---	01 No.		
	Function	---	To prevent Damage due to accidental vacuum in the steam generator.		
35.	MMI				
	Model	---	As Per your Specification		
	Printer Port	---	Rs 232		
36.	Printer				



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URS No.:

S.No.	Name of the Component	MOC	Technical Specification
	Model	---	LX 310
37.	Strip Chart Recorder		
	No of Channels	----	Six
	No & Type of Inputs	----	6 (5T + 1P)
	Temperature:	----	5 Nos, Pt100, 3 Wire
	Range	----	0 to 200°C
	Pressure	----	1 No, 4 - 20 mA
	Range:	---	-1 to 3 bar
38.	PLC		
	Model	---	FX1N 24MRES
	No of digital inputs	---	14 Nos
	No of digital inputs used	---	10Nos
	Type of input	---	24 V DC
	No of digital outputs	---	10 Nos
	No of digital outputs used	---	10 Nos
	Type of output	---	Potential Free Relay
	Function	---	To control the process automatically
39.	ANALOG INPUT CARD		
	No of Analog inputs	---	2
	No of Analog inputs used	---	2
	Type of input	---	4-20 Ma Signal
40.	ANALOG I/P CARD	---	
	No of Analog inputs	---	2
	No of Analog inputs used	---	2
	Type of input	---	PT 100 Wire Signal
41.	EXTENSION CORD		
	No of digital outputs	---	8
	No of digital outputs used	---	6
42.	PRESSURE TRANSMITTER		



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S.No.	Name of the Component	MOC	Technical Specification
	Model	---	As per your specification
	Range	---	0-4 bar
	O/P	---	4-20 mA
	Qty.	---	01 Nos
43.	TEMPERATURE INDICATOR CUM CONTROLLER		
	Make /model	---	Radix / Prima 721
	Range	---	0 to 200 °C
	Qty.	---	01 No
44.	TEMPERATURE SENSOR		
	Type	---	Pt-100 /Duplex/3 wire /Flexible
	Size	---	To suit the process requirements
	Length	---	
	Accuracy	---	
	Qty.	---	
45.	D.C. SOURCE		
	Outputs voltage	---	24 V DC
46.	ELECTRIC CONTROL PANEL & POWER		
	Type	SS304	Inbuilt front Panel
	Switch gear	---	<ul style="list-style-type: none"> • Contactor – Siemens • Miniature Circuit Breaker – Siemens • Over Load Relay – Siemens • Rotary switch - Siemens • Key switch - Siemens • Indication Lamp – Siemens • Terminal Block – Connect well
47.	SAFETY FEATURES & ALARMS		
	Doors Inter Locks		<ul style="list-style-type: none"> • The two doors are interlocked electrically, that prevents both the doors from opening simultaneously. • When the process is on, the door is



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			<p>locked electrically and this prevents the door opening when the process is ON.</p> <ul style="list-style-type: none"> To start the process, the door close positions (for both doors) act as preconditions for the process. Unloading side door will open only after satisfactory completion of the process. Door Obstruction Safety: the door will retract to open if obstructed by hand or any other object.
	ALARMS		<p>Alarms will be on if</p> <ul style="list-style-type: none"> If chamber vacuum leak test is failed. If the chamber temperature overshoots. If chamber temperature falls below specified level & the timer stops counting. If chamber temperature falls further below specified level & the timer resets previously counted time. Plant steam, pure steam, process water, cooling water & process air pressure low Chamber pressure high Too long time for heat up Too long time for pre vacuum Too long time for post vacuum Vacuum pump trip. Too long time for pre pressure Too long time for cooling Door Precondition fail Air ballasting pressure low
48.	CARRIAGE	SS316L	As per your specification and Finalized Purchase



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S.No.	Name of the Component	MOC	Technical Specification
49.	TROLLEY	SS316L	order.
50.	Earthing	---	Whole body Earthing
	Utilities		
	Electrical configuration & cabling		
	Power Supply	-----	As per your specification and Finalized Purchase order.
	Power cable	-----	
Power / Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.	

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:



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➤ **FUNCTIONAL REQUIREMENTS:**

- Leak testing cum terminal sterilizer shall comply as per ISPE, cGMP, cGEP Guidelines.

➤ **RELIABILITY AND AVAILABILITY:**

- The system shall be available for continuous operation.
- Material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

➤ **MAINTENANCE:**

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- 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.



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8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

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

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, Operation & cleaning procedure for **Leak testing cum terminal sterilizer**, Assembly and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation & Calibration at the site.

8.4 DELIVERY:

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification (MOC & Calibration Certificates) and Operation Manual in Soft as well as Hard Copy.



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9.0 DOCUMENTS TO BE PROVIDED:

- 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

Note: The whole URS is a tentative document. Manufacturer or Vendor will be solely responsible for performance of machine specified in the catalogue or during discussion at the time of finalization of purchase order. Specifications and details mentioned in the DQ, duly signed by Vendor/ Manufacturer and duly signed by Head QA will be treated as final specifications of the machine.

The said DQ will be treated as an integral part of purchase order.



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10.0 REVIEW COMMENTS:

- For any changes in the design/make of the **Leak testing cum terminal sterilizer** 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)



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11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
HP	:	Horse power
TPF	:	Three Piece Filling machine
Hz	:	Hertz
AC	:	Alternative Current
SS	:	Stainless Steel
MMI	:	Man Machine Interface
Qty	:	Quantity
mA	:	Milli Ampere
LPM	:	Liter per Minutes