USER REQUIREMENT SPECIFICATION FOR STERILIZING & DEPYROGENATING TUNNEL

LOCATION:	**DRY POWDER LINE**
SUPERSEDES URS No.	**NIL**

URS CONTENTS

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 sterilizing & depyrogenating tunnel 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 sterilizing & depyrogenating tunnel
- 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 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 Autoclave cum bung processor 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 depyrogenating tunnel is to depyrogenate the glass vial for Sterile Dosage Forms.

Depyrogenating tunnel 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:

- Depyrogenating tunnel shall be able to depyrogenate the glass vial for sterile dosage form .
- The Sterilizing and Depyrogenation Tunnel is a complete Automatic control System with the basic unit mounted on stainless steel stand. The Equipment comprises of four zones, Drying, Sterilizing, and stabilizing and cooling zones. The de-pyrogenation and sterilization is achieved under class 100 with a positive pressure gradient. The Equipment is designed to achieve complete sterility and a 3 log reduction in endotoxin content.

6.1 TECHNICAL SPECIFICATION:

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
1.0	**Drying Zone:**		
	Length of the drying zone		Approx 700-750 mm
	Air Discharged Approx.		670 m^3/ hr
	Material of Construction		SS304
	Air Velocity 200 mm below HEPA		0.45 ± 0.1 m/s
	Pre-Filter		5 micron
	Qty.		02 Nos.
	Blower		
	Qty.	---------	01 No.
	Capacity	---------	As per equipment requirement
	Motor		
	Capacity	---------	As per equipment requirement
	RPM	---------	As per equipment requirement
	Qty.	---------	01 No.
2.0	**Sterilizing Zone**		

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
	Blower		
	Qty.		01 No.
	Length of the d Sterilizing Zone		Approx 1450-1500 mm
	Air Discharged Approx.		1415m^3/ hr
	Material of Construction		SS304
	Air Velocity 200 mm below HEPA		0.45 ± 0.1 m/s
	Pre-Filter		5 micron
	Qty.		02 Nos.
	Capacity		As per equipment requirement
	Motor		
	Capacity	---------	As per equipment requirement
	RPM	---------	As per equipment requirement
	Qty.	---------	01 No.
3.0	**Exhaust Blowers**		
	Vapour Exhaust		
	Qty.	---------	01 No.
	MOC	--------	MS Powder Coated
	Cooling Zone Exhaust		
	Qty.	---------	01 No.
	MOC	--------	MS Powder Coated
4.0	**Operating Parameter**		
	Temperature	--------	121-134^{0}C
	Pressure	--------	Approx 1.2-2.1 kg/cm^2
	Vacuum	--------	Full
5.0	**Compound Gauge**		
	Range	--------	Range - 1 to 6 To 6 kg/cm2 (g)
	MOC	--------	SS316L for Contact Part

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
			SS304 for Non Contact Part
	NO.	--------	02
6.0	**Validation Port**		
	MOC	SS316	As per CGMP Requirement
	NO.	--------	2 Nos.
	NO of sensor arrangement		No of sensor arrangement in each port : 8
7.0	**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
8.0	**Switches**		
	Pressure switch	--------	02 Nos.
	Vacuum switch	--------	02 Nos.
	Photo cell sensor	--------	2 No. for door obstruction safety
9.0	**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
10.0	**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

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
11.0	**Safety**		
	Door inter lock	--------	Both the door should not opened simultaneously
	Door obstruction	--------	Door shall be obstructed by hand
12.0	Temperature sensor (Inside the chamber)	Pt 100	Make - radix Accuracy - Class A Qty – 04 Nos. Range – Approx
13.0	Air filter	--------	0.2 micron
14.0	Temperature indicator controller	--------	Range – 0 to 200 ° C Make – Radix Qty -01 No.
15.0	Extension card	--------	As per your specification
16.0	Printer	--------	Dot matrix Online printer
17.0	**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.
- Autoclave cum bung processor shall comply with the "Current Good Manufacturing Practices".

7.3 UTILITY REQUIREMENTS:

- System shall accept Three Phase 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 Autoclave cum bung processor 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.

Reviewed By
Manager Engineering
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