USER REQUIREMENT SPECIFICATION

FOR

DEPYROGENATION TUNNEL

LOCATION	**Ampoule line**
SUPERSEDES URS No.	**NIL**

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR DEPYROGENATION TUNNEL	U RS No.:

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PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR DEPYROGENATION TUNNEL	U RS No.:

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 :

- This URS has been initiated by …….. and pertains to procurement of Sterilizing and depyrogenating tunnel**.**
- 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 Ampoule filling Machine 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 Sterilizing and depyrogenating tunnel Machine.
- 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 …….., will become a Contractual Agreement between Vendor and ……..
- 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 ……..

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Sterilizing and depyrogenating tunnel Machine of …….
- 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 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	• 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	• Review of User Requirement Specification for compliance with the Product Requirement.
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Sterilizing and depyrogenating tunnel is to to achieve depyrogenation of various sizes of glass ampoule at specified temperature, speed and time. Perform depyrogenation washed ampoule as well as drying and cooling of Ampoules.

- Sterilizing and depyrogenating tunnel should complies with the "Current Good Manufacturing Practices".
- Schedule–M "Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products".

6.0 SYSTEM OVERVIEW:

Sterilizing and depyrogenating tunnel machine which consists of Drying zone, Hot zone and cooling zone Process.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	-----	Sterilizing and depyrogenating tunnel
2.0	Modal /Type	-----	Should be in compliance with cGMP.
3.0	Overall Size of the Machine	-----	As per your specification
4.0	Top & bottom frame	SS 316 L	As per cGMP Requirement
5.0	Capacity	----------	1 to 5 ml ampoule
6.0	Type of model	----------	Tunnel with conveyor width of 900 mm confirming to current CGMP requirements
7.0	Quantity	----------	01
8.0	Machine specification	-----	All contact part of the machine like conveyor belt, HEPA mounting frame, hot zone inlet, outlet isolating plate and infeed, out feed dead plate etc. should be SS 316L and non -contact parts should be SS 304.
			Machine should be covered with SS 304 guide panel on all side.
			Machine should be compact and easily cleanable.
			Machine should be operated through PLC mounted on separate electrical control panel.
			Machine should be provided with validation port for testing of HEPA filter.
			Machine should have hermetically sealed type view port in drying zone, cooling zone and in stabilization zone.
			Machine should be provided with stainless steel 304 diaphragm plate for isolating the sterile area from sterilization area.
9.0	Function requirement specification	----------	Machine should be operated by manual and auto mode on PLC
			Machine should be PLC based control with back

S.No.	Name of the Component	MOC	Technical Specification
			Lit alphanumerical display HMI with data logging and printing facility.
			Machine should consist of four sections. • Drying zone • Sterilizing zone • Cooling zone • Stabilization zone
			HMI should display all operational status mimic like • LAF on/off • Blower on/off • Turbine on/off • Conveyor on/off • Individual heater bank on/off status.
			Control panel should be made in SS304
			Operating the tunnel through PLC should be accessed through password and change of values in set parameter should access through different password level.
			Provision should be provided for cooling the air discharging from cooling zone to avoid the excess heat load and additional filtration load on HEPA filter.
			Exhausting of dry zone air should be passed through HEPA filter.
			Four Magnehelic gauges should be provided for each zone for measuring differential pressure.

S.No.	Name of the Component	MOC	Technical Specification
			All fault indication should be displayed in alarm list and should have Visual display on control panel or in PLC.
			Individual heater bank fault should be identified in alarm list and should have visual display in PLC.
			Hot HEPA withstanding temperature should not less than 400°C & Skin temperature of the tunnel sterilizer should be less than 45°C
10.0	Operational interlocking facility	-----	• Emergency stop button should be provided in the control panel. • Conveyor off for more than 30 mins (time settable), heater bank should automatically off and restart after manual reset. • Conveyor stops – Maximum Ampoule accumulation at tunnel in-feed – washing machine stop. • Conveyor starts – Minimum ampoule accumulation at tunnel infeed – washing machine start. • Out feed tunnel maximum accumulation – conveyor stop.
11.0	Indexer	-----	As per your specification
12.0	Machine body	SS316L	Contact Parts
		SS304	Non Contacts
13.0	Motor	-----	As per your specification & suits for equipment design
	Vibrator Controllers	-----	As per your specification & suits for equipment design
14.0	Emergency Switch	-----	Push Button

S.No.	Name of the Component	MOC	Technical Specification
15.0	Safety Features	-----	• Separate electrical control panel with double earthling provision • Emergency OFF switch. • All electrical wires should be given appropriately number and identified and covered with guard. • Safety guards on all four sides. • All moving parts should be properly covered. Control panel should be provided with high/low voltage protection facility.
16.0	Indicating lamp	-----	As per your specification
17.0	Safety Guard	-----	As per your specification
18.0	Earthing	-----	Whole body Earthing
19.0	Special feature	-----	As per Purchase order.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Sterilizing and depyrogenating tunnel machine shall comply as per ISPE, cGMP, cGEP Guidelines.

7.2 RELIABILITY AND AVAILABILITY:

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

7.3 MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- 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 Sterilizing and depyrogenating tunnel Machine, 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.

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.
- 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.

10.0 REVIEW COMMENTS:

- For any changes in the design/make of the Sterilizing and depyrogenating tunnel Machine if not as per the URS, prior intimation/approval should be taken by the supplier from ……..
- 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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
GA	:	General arrangement
QA	:	Quality Assurance
No.	:	Number
GMP	:	Good Manufacturing Practices
Sr.	:	Senior
SS	:	Stainless steel
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
Min	:	Minute