



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Double Door Steam Sterilizer

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 7

Name of Instrument: Double Door Steam Sterilizer

Document Reference Number:

Effective Date:



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1.0 Approval:

Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	Signature	Date
Checked By	Signature	Date
Reviewed By	Signature	Date
Approved By	Signature	Date



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3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a double door steam sterilizer.

The URS shall be recognized as the integral part of the procurement agreement with the selected equipment vendor. The equipment supplier or vendor shall abide by the information and condition set forth by this document as well as purchasing and delivery terms and conditions of Client.

The steam sterilizer shall be interfaced with fully PLC control system.

This is used to sterilize the material

4.0 OVERVIEW DEFINITION

4.1 The Double door steam sterilizer shall have the following features:

- 4.1.1. The double door steam sterilizer shall have updated with fully PLC controlled and parallel manual mode.
- 4.1.2. The double door steam sterilizer shall be designed minimum three label password protection.
- 4.1.3. The double door steam sterilizer shall be designed to provide on line printing facility.
- 4.1.4. The double door steam sterilizer shall be provided four temperatures and one pressure point.
- 4.1.5. The chamber shall be provided with direct % RH electronic capacitor type humidity sensors which will avoid wick and water.
- 4.1.6. The double door steam sterilizer should have a provision for aborting the cycle with operator label password.
- 4.1.7. The double door steam sterilizer should have the temperature control during the sterilization period within the limit of ± 1 °C.

4.2 The double door steam sterilizer shall be used for:

For the steam sterilization of materials

4.3 Technical Specifications:

- 4.4.1 Chamber Size** : 600 (W) x 600 (H) x 1200 (D).
- 4.4.2 Thickness of Chamber** : 6 mm.
- 4.4.3 Operating temperature & Pressure** : 121°C,(1.2 kg / cm²)



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4.4.4 Operating mode : PLC controlled & manuals

4.4 The machine is to be used at the following environmental conditions:

4.4.1 Temperature : Ambient

4.4.2 Relative Humidity: Ambient

4.5 Base Utilities Available:

- Compressors
- Vacuum pump
- Pressure reducing valve
- On line printing facility
- PLC

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The double door steam sterilizer shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall shut off automatically. The system requires operator innovation to restart.

5.3 SAFETY FEATURE:

The system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

The system shall have an Emergency alarming facility. Incase any parameter goes up or down from set parameter. The double door sterilizer shows all parameter over display screen as well as on line printing paper.



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6.0 SALIENT FEATURES

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The Supplier shall utilize Programmable Logic Controller that shall include a communication port.

UTILITIES:

The Supplier shall specify utility requirements. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.

6.2 MATERIAL OF CONSTRUCTION:

- MOC chamber** : SS316
- MOC jacket** : SS304
- MOC door & sterilizer** : SS304

7.0 MAINTENANCE:

Do's and Don'ts to be provided

- 7.1 Preventive maintenance system and checks to be provided (Maintenance and operation manuals of vendor equipment)
- 7.2 A comprehensive lubrication list and recommended lubrication schedule
- 7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)
- 7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals., DQ, Electrical drawing

8.0 DELIVERY:

The steam sterilizer with all options, equipment, and the documentation listed below, shall be delivered to Client Site.

Delivered should be confirmation of the purchase order



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9.0 DOCUMENTATION:

9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting “as-built” condition with final delivery.

9.2 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect “As-Built” condition.

9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:

9.4 Design qualification

9.5 Installation Qualification

9.6 Operational Qualification

9.7 Maintenance and service manuals

9.8 Instrument listing

9.9 Material of construction