USER REQUIREMENT SPECIFICATION	
NAME OF ITEM: Autoclave	**PROTOCOL No**:.....
FUNCTIONAL AREA: Production	**Page No.:** 1 of 1

USER REQUIREMENT SPECIFICATION
AUTOCLAVE

URS No.: ……..

DEPARTMENT NAME: PRODUCTION

USER REQUIREMENT SPECIFICATION

The User Requirements Specifications for the Autoclave has been reviewed and approved by the following for initiation of procurement:

URS PREPARATION

DEPARTMENT	NAME	SIGNATURE / DATE
User Department		

URS REVIEW

DEPARTMENT	NAME	SIGNATURE / DATE
User Department Head		
Engineering Department		

URS APPROVAL

DEPARTMENT	NAME	SIGNATURE / DATE
Quality Assurance		

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1.0 INTRODUCTION

- This User Requirement Specification has been initiated by the ……., and pertains to the procurement of the Autoclave.
- Being end user of the proposed equipment, Production department initiated the document, which shall be reviewed by Head user department, Engineering and approved by Quality Assurance.
- This document shall help the supplier for developing the functional requirement specifications and design specification, which on approval by ……. shall become a contractual agreement between the supplier and ……..
- The URS shall also help the supplier in understanding the end user requirements in details.

2.0 OVERVIEW

This document encompasses the normal range of equipment operations. This section should be expanded to provide a high level description of the system explaining why it is required and what is required of it. Include the background, key objectives, and the main functions and interfaces. Obviously, technology improvements and new applications may require deviation from this template.

The facilities, upon completion, shall be in compliance with Schedule 'M' (India) and all international regulations and standards like USFDA, ANVISA (Brazil), TGA, UK MHRA, WHO etc.

The equipment should comply with the following guidelines/standard:

The Sterilizer design confirms to the specifications and requirements as specified in cGMP features, & guidelines from ASME, Section VIII, Div.-I and EN 285 guidelines. AISI 316L grounded & polished Chamber is mounted on SS 304 tubular skid.

The sterilizer chamber is rectangular in shape with crevice free smooth rounded corners and smooth surface. Internal surface finish of chamber is mechanically polished to 0.6 Ra and pipeline internals are mill polished. All nozzles and pipelines are interconnected with sanitary fittings and orbital welded.

The radiation from the chamber is prevented by SS316L jacket along with thermal insulation the jacket provided is "Dimple construction". The Chamber, jacket and doors are designed as per the code for pressure vessels laid in ASME guidelines. With dimple construction, increased the heat transfer efficiency and structural strength is attained, which in turn saves on the jacket steam consumption.

The sterilizer is covered in SS304 Cabinet which forms complete box type Construction using quickly removable hinged paneling on complete surrounding. Isolation panel (Cross Contamination Bio-Seal) made of SS304 Sheet is provided with Flush Mounting arrangement on the sterile side enables Complete Isolation of sterile and non-sterile area.

GMP-Regulations:

- EU-GMP-Guideline Part 1, Annexes 1, 15 & 17

- Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs; General
- 21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals
- 21 CFR Part 11: Electronic Records; Electronic Signatures

FDA Guidance for Industry

- Sterile Drug Products Produced by Aseptic Processing
- Documentation for Sterilization Process Validation

GAMP

- The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 4

ISO

- ISO 14644 – 1 (For Cleanliness Class)
- ISO 14644 – 3 (For HEPA integrity testing)

Vertical Sliding Door:

Door opening and closing is by pneumatic cylinders. The door slides downward to open in the Vertical sliding mechanism. For specific requirements this arrangement is modified to suit the equipment and the site conditions. The doors are insulated and SS 304 cladding is provided. Door safety arrangement is included for opening and closing operations. The functions of these pneumatic cylinders are controlled through the PLC to ensure the safety of the operator and the equipment during the entire operation. Door sealing is done by pressurized hollow tubular gasket. The gasket is retrieved by vacuum arrangement before the door is allowed to open. The complete sequence and the door interlocks are also controlled by PLC.

Insulation:

All the external surfaces are insulated (except where insulation would interfere with the function and operation of the sterilizer), to minimize the heat transmission to the environment such that the temperature of the outer surface does not exceed 55 °C considering the ambient temperature of 25 °C.

Sampling valve is provided in chamber drain line for testing of condensate quality. Internal surface finish of chamber is mechanically polished to 0.5 Ra and pipeline internals are mill polished. All nozzles and pipelines are interconnected with sanitary fittings and orbital welded.

Other Features & Benefits:

Two separate temperature sensors are provided at drain for temperature recording and controlling the cycle. By separating the sensors, the trouble shooting is simplified and complies with the latest cGMP guidelines. Pressure transmitter along with the signal distributor is provided for recording the chamber pressure. Chamber pressure is constantly monitored and recorded.

Condensate level sensor and control valve:

Level sensor at drain with control valve and alarm through PLC. This will reduce the initial heat up time in the cycle by allowing large quantity of condensate to drain. Water accumulation in drain line is constantly monitored and in such case alarm is given during sterile hold period. In case of failure of the steam trap and strainer this arrangement will enable to continue the functioning of sterilizer. Validation ports with suitable nozzles for flexible sensors are provided on the side wall for multi-point temperature mapping. All drain lines are connected to a common drain header.

With PLC controlled arrangement following standard cycle are provided:

⇒ Chamber Leak test Cycle

⇒ Bowie & Dick test Cycle

⇒ HPHV Cycle.

⇒ Standard Cycle.

3.0 GENERAL INFORMATION

S. No	DESCRIPTION	DETAILS			
3.1	Name of Equipment	Autoclave			
3.2	Equipment Make / Model	M/s. …….			
3.3	Purpose of equipment	Steam sterilizers used for sterilizing various loads like machine components, garments, containers, media fills for sterility testing and similar applications			
3.4	Working Capacity/ Output / speed	Width - 600mm Height - 600 mm Diameter - 1200 mm			
3.5	Process Requirements	Utility	Quantity	Pressure / Quality Required	Temperature
		Pure Steam (Peak flow rate considering Chamber)	66 Kg/Hr	1.5 kg/cm^2	-
		Pure Steam (Peak flow rate considering Jacket)	33 Kg/Hr	1.5 kg/cm^2	-
		Pure Steam (Consumption for chamber per cycle)	22 Kg	1.5 kg/cm^2	-
		Pure Steam(Consumption for Jacket per cycle)	11 Kw	1.5 kg/cm^2	-
		Electrical Load	3 Kw	-	
		Soft water for vacuum pump	5 lpm	0.7 kg/ cm^2	10-15°C
		Compressed air	7 cfm	8kg/cm^2	ambient

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4.0 COMPONENTS DETAILS:

Pressure Vessel:		
Parameter	**Chamber**	**Jacket**
Operating pressure	2.1 kg/cm^2	2.1 kg/cm^2
Design pressure	2.31 kg/cm^2	2.31 kg/cm^2
Test pressure	3 kg/cm^2	3 kg/cm^2
Operating temperature	122°C	121°C to 135°C
Design temperature	150°C	150°C
MOC Details		
Component	**MOC**	**Thickness**
Chamber	SS316L	6 mm
Jacket	SS316L	4 mm
Door	SS316L	14 mm
Insulation	RBFG	75 mm
Insulation Cladding	SS304	20 G
Piping	SS316L	-----
Skid	SS304	-----
Process Specifications		
Parameter	**Minimum**	**Maximum**
Sterilization temperature	121°C	135°C
Sterilization Holding Time	15 min	30 min
Chamber Pressure	1.14 kg/cm^2	2.14 kg/cm^2
Door Open temperature	45°C	-----
Component Details		
Name of the Component	**Specification**	**Requirement**
Control Valve	On off type Ball valve pneumatically actuated	06 Nos
Duplex temperature sensor	PT 100 at Drain	01 Nos
Pressure switch for Air	Make: Orion Range: 0.51 to 7.14 kg/cm^2 MOC: Brass, Diaphragm type	02 Nos
Gasket Vacuum Switch	Make: Orion Range: -100 to -1000 mmHg MOC: Brass, Diaphragm type	01 Nos

Pressure transmitter	Make: Keller Range: -1.0 to 3.06 kg/cm^2 Model: 23R	01 Nos
Pressure gauges Jacket	Size: 4″ Dail SIze Range: 0 to 4.0 kg/cm^2 Make: Waree	1Nos. per Door
Compound Gauge for Chamber	Size: 4″ Dail SIze Range: -1 to 3.5 kg/cm^2 Make: Waree	1Nos. per Door
Safety valve	¾″ BSP, SS 316L Make : Shakti	2 Nos
Non returns valves for Chamber Vacuum	Make: VB	1 Nos
Pneumatic components	Make: Festo / SMC / Micro Pneumatics	Set
PLC	Mitsubishi	1 Nos
MMI	E-1012 , Two line display	1 Nos
Air Pressure Regulator	FRL - ¼″ , Make : SMC / Festo	1 Nos

5.0 SYSTEM CONTROL

S.No.	Component(s) / Feature(s)	Required (Yes / No)	Description (as applicable)
5.1	Control Panel	Yes	To control all the automatic valves and power supply
5.2	Protection Class	NA	-----
5.3	Indicator(s)	Yes	To know the status of process
5.4	Alarms and Warnings	Yes	To identify the errors
5.5	Data security	Yes	To maintain the proper Data
5.6	MMI / HIM and PLC Details	Yes	To control the all operations / cycles
5.7	User interface –compatible to SCADA system.	NA	-----
5.8	Interface to other system (s) / equipment (s) / instrument (s)	NA	-----
5.9	Data storage Capacity	Yes	To store the data for reference
5.10	Password Protection	Yes	To avoid the unauthorized operations
5.11	Others	NA	-----

6.0 SAFETY FEATURES: APPLICABLE/NOT APPLICABLE

S.No.	Safety Feature(s)	Required (Yes / No)	Description (as applicable)
6.1	Emergency Stop	Yes	To abort process during Emergency situation

6.2	Power Failure / Recovery	Yes	For product / equipment safety
6.3	Electrical Protection (Flame Proof / Non Flame Proof)	Yes	To avoid the electrical short circuit
6.4	Alarms & warnings	Yes	To identify the errors
6.5	Earthing	Yes	To avoid the electrical short circuit
6.6	Noise level	Yes	Personnel Protection
6.7	Interlocks	Yes	Equipment / personnel safety
6.8	Door opening safety	Yes	Personnel Safety
6.9	Others	NA	-----

7.0 DOCUMENTATION: APPLICABLE/NOT APPLICABLE

Installation, operation, and maintenance instruction documentation for the system shall be developed to a level that is comprehensible to a high school graduate.

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

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.

All documents shall be supplied with hard copies, and electronic versions supplied in the format identified for each document:

S. No.	Title	Required (Yes / No)	Description (as applicable)
7.1	Project Plan	Yes	Hard copy and Microsoft Word (*.doc)
7.2	Functional Specification/Requirement	Yes	Hard copy and Microsoft Word (*.doc)
7.3	Design Specifications	Yes	Hard copy and Microsoft Word (*.doc)
7.4	Catalogues (Original manufacturer’s catalogues with information of technical specs, product description, material description, characteristics, performance profile, schematic diagrams, and other diagrams)	Yes	Hard copies for all major components
7.5	Calibration certificates (for all instruments)	Yes	Hard copy
7.6	Material of construction certificates (For all contact parts, critical parts wherever applicable)	Yes	Hard copy
7.7	Test/Performance certificates for all critical components	Yes	Hard copy
7.8	Controls Test (Procedure and specifications)	Yes	Hard copy and Microsoft Word (*.doc)

S. No.	Title	Required (Yes / No)	Description (as applicable)
7.9	Hardware Installation Test (Procedure and specification)	Yes	Hard copy and Microsoft Word (*.doc)
7.10	Operational Test	Yes	Hard copy and Microsoft Word (*.doc)
7.11	Factory Acceptance Test	Yes	Hard copy and Microsoft Word (*.doc)
7.12	Operator, Maintenance and Service Manuals	Yes	Hard copy and Microsoft Word (*.doc)
7.13	Process and Instrumentation Diagram (P&ID)	Yes	Hard copy and AutoCAD version (*.dxf)
7.14	Instrument Listing	Yes	Hard copy and Microsoft Word (*.doc) or Excel (*.xls)
7.15	Control Schematics	Yes	Hard copy and AutoCAD version (*.dxf)
7.16	Control Panel Assembly Drawings	Yes	Hard copy and AutoCAD version (*.dxf)
7.17	Equipment Assembly Drawings	Yes	Hard copy and AutoCAD version (*.dxf)
7.18	Bill of Materials	Yes	Hard copy and Microsoft Word (*.doc) or Excel (*.xls)
7.19	Spare Parts List	Yes	Hard copy and Microsoft Word (*.doc) or Excel (*.xls)
7.20	Component Cut Sheets test reports	Yes	Hard copy
7.21	Flow chart for PLC program	Yes	Hard copy and Microsoft word (*.doc)
7.22	PLC manual (includes screen sequencing, alarming, operating ranges, etc)	Yes	Hard copy and Microsoft word (*.doc)
7.23	CONTROL PLATFORM Program Printout and Disk File	Yes	Hard copy and Program Development format
7.24	OIP Configuration Printout and Disk File	No	Hard copy and Program Development format

8.0 OTHERS

S. No.	Title	Required (Yes / No)	Description (as applicable)
8.1	Training	Yes	To train the operating personnel for proper operation and to avoid the unwanted operations.
8.2	Inspection at manufacturer's end	Yes	To exam the equipment against URS
8.3	Technical support	Yes	To installation and operation of the equipment as per requirement
8.4	Others	NA	-----

9.0 URS ACCEPTANCE BY THE VENDOR:

The User requirement specification has been discussed and agreed upon. We hereby declare that we will supply the equipment / system as per above laid down specification.

Name of the Vendor	Signature/Date