USER REQUIREMENT SPECIFICATION

EQUIPMENT: DRY HEAT STERILIZER

EQUIPMENT ID:……

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A) APPROVAL SIGNATURE

Signature in this page indicate the agreement with the User Requirement Specification of Dry Heat Sterilizer described in this document. Should changes required, the document shall be revised and approved.

Name/Designation	Signature	Date
Prepared By		
Checked By		
Approved By		

B) REVISION HISTORY

Revision No	Date	Revision Summary
00		First Issue

COMMITMENT

This document contains the specification, called as User Requirement Specification, required as a basis of designing any equipment or system to be purchased or fabricated from any external agency. This specification is approved by the competent staff of ……, who are trained or experienced on the process and regulatory requirements. This User Requirement Specification is prepared to document the expectation of ……from suppliers of the equipment or system, which should be suitable to the process and regulatory requirement and to comply the performance criteria established by the …….

……..appoints Project manager to purchase the equipment or system for its manufacturing/testing facility. Project manager sends this specification to number of suppliers, who are suitable to supply or fabricate the equipment or system. It is the expectation of project manager to receive the response of suppliers on their capability to supply the equipment or system as per the specification described in this document. In case if it is not possible to comply all specification, project manager shall discuss with the reviewing and approving authority of URS for change in the specification. A revision in the user requirement specification shall be done and approved. The reason for the change shall be written in the revision summary.

Based on the suppliers response, a detail engineering specification called as Design Specification (DS) shall be prepared and shall be compared with URS by competent team of Quality Assurance to check that all specification of URS have been considered in DS. This DS shall be used for preparing the Purchase Order. The URS and DS shall be confirmed in Installation, Operational and Performance Qualification test.

All equipment specification reflects the approach of ……. to comply all GMP requirement and Health regulatory norms, [e.g. CFR 21.211 (US); Orange Guideline (UK); Schedule M of drug and cosmetic act (India)] of all countries where the company wants to sell its product. Following are general GMP requirement but not limited to, which shall be complied in all equipments

1) The contact surface shall not be reactive, additive or absorptive to such an extent that it will affect the quality of the product thus present any hazard.
2) The material of construction should not shed particles and should be compatible to stressed condition of the process.
3) The equipment shall not contribute any particulate contamination or lubricant oil to the product processed in the equipment.
4) The equipment shall have the facility of cleaning of its contact and noncontact parts.
5) No screw type joint should be there in contact areas
6) There should not be dust accumulating location like crevices

7) Equipment should have the facility to qualify it complying all process and regulatory requirement
8) All instruments used in the equipment should be supplied calibrated with traceability to any national standard
9) The automated equipment shall have the sequencing and security system in accordance with process.
10) The equipments used for any aseptic processing should be suitable for sterilization of contact parts
11) The equipment design shall consider the process, environment and operator safety.

Note: The word 'user' used in this document indicates ……..

C) SPECIFICATIONS:

This form is to be filled as a part of Design Qualification program. Blank form shall be in the electronic format. Topics area are shaded and written in Bold Times New Roman Font (Size 12). Fill the form in unshaded space given just below or beside the topics. Type with Normal Times New Roman Font (Size 12) without any shaded background.

1.0 BASIS OF DESIGN

1.1 Name of the Equipment

DRY HEAT STERILIZER

1.2 Use of the Equipment

The Equipment is used for sterilizing and depyrozinating the canisters, Sampling aids and other metallic items which will be used in sterile area

1.3 Operation (write how does equipment operate to provide desired operation)

Equipment is provided with one double door chamber. One door opens at non-sterile side and other door opens at sterile side. Chamber is provided with air suction blower which sucks the air through HEPA filter and pass the air through Heater. Heater increase the temperature suitable for sterilization and depyrogenation. The equipment design facilitate the recirculation of air and maintenance of heater temperature, which in turn provides uniform temperature in the chamber and in the articles placed in the chamber. Sterilization and depyrogenation takes place at temperature of 250°C when maintained for 45-60 minutes.

1.4 Input used and output produced. Mention the physical property of inputs/outputs which will be suitable for engineering design of equipment. Mention specifically if any input/in-process material/ finished product may hamper the equipment or any product quality may be affected by the equipment.

1.4.1 Input used:

Load articles:

a) Aluminium canisters (32 Nos. of 300 x 340 mm size and 16 Nos. of 300 x 468 mm size.) Approx. size.

b) Sampling aids.

Sterilizing agent: electrically heated 0.3µ filtered air

1.4.2 Output Produced:

Sterilized and depyrogenated articles

1.5 Process Description

1.5.1 Charging of input:

Loading of input shall be through carriage and trolley from class 10,000 area

1.5.2 Process(preferably demonstrate with flow chart)

a) Start the blower and open the supply and return dampers in auto mode through PLC

↓

b) Heaters should be switched on through PLC

↓

c) Close/ Shut off the dampers (Supply & Exhaust) at a pre set temperature e.g. 120°C through PLC to remove the moisture from load.

↓

d) Keep the heaters on for Sterilization hold period at 260°C for maximum of 120 minutes (subject to validation)

↓

e) Start the cooling cycle . Switch off the heaters, open the supply and exhaust dampers until the temperature reaches to preset temperature.(e.g. preset temp.70°c)

↓

f) End of the cycle.

1.5.3 Discharging of output

Unloading of sterilized and depyrogenated articles from a carriage shall be done at aseptic class 100 area under unidirectional air flow zone.

1.6 Batch size

Not applicable

1.7 Output per day

Two to four cycles per day

1.8 Total operation time per day

12 to 16 Hrs/day

1.9 Centre of operation (local and/or distant)

Local

1.10 Operator involvement

- Article loading
- Article unloading
- Program selection through Man Machine Interface
- Cycle initiation

1.11 Effect on environment

Effect on environment to be controlled by suitable design of insulation thickness. Environmental condition is given in section 1.12.3

1.12 Environment Of Installation

1.12.1 Allocated floorspace with allocated corridor around the periphery of the equipment

Allocated floor space: Sufficient working space towards and nonsterile area side.

1.12.2 Vertical clearance

Total Room Height: Sufficient space for HEPA filter placement is required.

1.12.3 Physical Condition	
Room Temperature	23±2°C
Relative Humidity	less than 55% (nonsterile side) less than 35%(sterile side)
Cleanliness and microbial status	Class 10,000 (nonsterile side) and Class 100 (aseptic side)
Hazard level	Non Flame proof area

2.0 STRUCTURAL DESIGN REQUIREMENT

2.1 Type:

Double door Dry heat sterilizer

2.2 Capacity

Inside dimension of the Chamber :900 x 1100 x 1330 mm

2.3 Material of Construction and surface finish of critical and contact parts	
Contact parts(metallic)	SS316L
Noncontact parts(metallic)	SS304
Gasket	Food grade Silicon

Surface Finish	Inside surface is smooth ,without any crevices.

2.4 Identified critical component (write with purpose, scope of supply and characteristics suitable to comply the GMP requirements)

Component	Name and particulars of the component	Scope of the supply
Main component	i.Chamber with Double door, ii.Blower fan with motor, iii.heaters, iv.cooling coils, v.Supply and return damper vi.HEPA filters.(For air in let, Chamber and exhaust.)	Supplier
Nozzles	Nozzle should be provided for vii.Filtered air viii.Validation port ix.Temperature sensor port	Supplier
Piping	All piping should be SS 316L, with Triclover joint.	Supplier
Attached component	i.Pressure module ii.PLC	Supplier
Controls	PLC	Supplier
Instruments	Details as per 2.5	Supplier

2.5 Instruments and their accuracy level

Instrument Name:	RTD	Magnehelic gauge		
Type of control :	Temperature control	Differential pressure control		
Purpose :	To monitor and control chamber temperature	To monitor the differential pressure across the HEPA filter and with in the chamber		
Operating range:	0 to 350°C	0 to 50 mm of WC		
Desired Accuracy:	±0.5°C	± 1.0 mm of WC		
Least count :	Not applicable	1.0 mm of WC		
Number:	Minimum 08	03		
Location :	All RTD's to be placed within the chamber.	One for chamber HEPA Module, and one for exhaust pressure module and one for chamber with respect to outside room		
Extent of Instrumentation:	Indication, control and Recording	Indication only		
Controlling Device :	PLC	NA		
Recording Device :	Strip chart recorder or batch printer	NA		
Least count of recording device:	0.5°C	NA		
Criticality of the instrument:	Critical	Monitor		
Documentation	Calibration certificate traceable to national standard and purchase reference catalog number			

2.6 Utility requirement and availability of utility with user

Utility Name	Specification	Purpose	Scope of supply	Supply location
Electricity	Voltage:415VAC Phase: 3ϕ Frequency: 50 Hz	For power to Blower motor and heaters.	User	PLC Panel board.
Compressed air	Pressure: 4-6Kg/cm²	for pneumatic operation	User	Pneumatic valve
Cooling Water	Ambient	For cooling coil to cool the chamber temperature.	User	Chamber

2.7 Design features for validation (if any)

The equipment should have two validation to insert flexible temperature probes.
The equipment should be provided with suitable nozzle to test DOP of HEPA filters and Non viable Particle count of the chamber in dynamic condition

3 FUNCTIONAL REQUIREMENT

3.1 Process control :

The equipment should have Programmable Logic Control system, which controls the process as described in 1.5.2

3.2 Design features for aseptic Processing (if any)

- The Dry heat sterilizer should be leak proof at closed condition.
- All the automatic valves should be closed when dry heat sterilizer chamber is not in operation.
- During operation chamber should have higher pressure of minimum 10 mm of WC

3.3 Design Features based on safety

3.3.1 Process safety

a) Door interlocking system: Two door should not be opened simultaneously
b) During operation door should not be opened.
c) Out of Specification audiovisual alarm system (refer point number 3.5.3)

d)

3.3.2 Operator and environmental safety	
Type of safety	**Specification**
Temperature withstand capacity	Not Less Than 350°C
Safety valve	NA
Rupture Disc	Not Required
Electrical Earthing	Required
Flameproof electrical connection	Not Required
Other (if any)	Door should be locked electrically during the cycle .

3.4 Cleaning/sanitization/sterilization requirement (CIP/COP/SIP/Automatic/Manual)

Dry heat sterilizer shall be cleaned in place manually with WFI from class 10,000 area side. From class 100 area side door moping shall be done.

3.5 Control requirements and level of automation (manual, semiauto, automatic, PLC, DCS, SCADA etc)

a) Cycle recipe : automatic though PLC .
b) Valve and Dampers operation: Pneumatic through PLC

3.5.1 Interface

Equipment shall be provided with Man Machine Interface with operator and supervisor and cable interface to external equipment i.e. computer or printer

3.5.2 Emergency stop

The system shall have an E-Stop (stay put) string designed to stop all physical movement / operation of the machinery immediately. The E-Stop buttons shall be located in easily accessible areas around the machine.

3.5.3 Alarms and warning

3.5.3.1 **Critical alarms" shall take action automatically to shut the equipment/system down and notify the operator through hooter. The operator shall be required to acknowledge the alarm before the alarm can be reset and the system restarted. Once the alarm is reset, the system may be restarted by the operator.**

i. In case the chamber temperature goes below the set temperature of sterilization hold period, the audiovisual alarm should be displayed.
ii. In case of low pressure or complete absence of compressed air, condition should be indicated as audio visual alarm.

3.5.3.2 "Process Critical alarms" shall notify the operator and place the system in a hold state to prevent product damage. Process Critical warnings and shall sound the alarm horn, illuminate the alarm indicator but allow the system to continue to operate. The operator shall be required to acknowledge the warning in order to silence the alarm horn, and the alarm indicator shall be extinguished when the warning condition disappears.

iii. In case the chamber temperature overshoots during sterile hold period the audiovisual alarm should be displayed on screen of PLC with reason.

3.5.3.3 "**Non-Critical warnings" shall notify the operator and take no further action. Non-Critical warnings and shall sound the alarm horn, illuminate the alarm indicator but allow the system to continue to operate. The operator shall be required to acknowledge the warning in order to silence the alarm horn.**

iv. Not applicable

3.6 Power failure and restart requirement

- The system will stop automatically upon loss of electricity, air, or other major utility and will require operator intervention to re-start.
- For automatic batch reporting system, the information shall be retained in the event of a power failure (A UPS is required for automatic batch reporting systems).
- An UPS shall be provided for PLC for automatic back up in case of electrical failure

3.7 Data acquisition system	
a) **Batch Recording**	Cycle history (Format attached) Strip chart recorder or data loger
b) Trend and saving	Required
c) Upload to company network	Not required
d) Language requirement in the system	English

3.7.1 Data and security	
Supervisor level	User Name and password with QA incharge for change in parameter through

	proper change control.

4 CONTAINMENT

4.1 Explosion Protection

Not required

4.2 Containment of the Product

Close/open system	Close
Aseptic System	Required
Leak proof	Required
Filtered air	Required
Filtered coolant in seal	Not applicable
Any other	Not applicable

5 SUPPORT REQUIRED FROM SUPPLIER

5.1 Pre-installation support

Supplier shall send one copy of equipment drawing, operational manual and Factory acceptance test protocol and specification.

5.2 Start-up support

i. Technical staff of supplier shall come to install the equipment and shall be present upto first three successful performance qualification run
ii. Technical staff of supplier shall train the applicable equipment operator of ……. before operation Qualification testing.
iii. Technical staff shall help ……to prepare the SOP of operation, cleaning and Preventive maintenance of the equipment.

5.3 Documentation (write Yes or No as required)

Document name	Yes/ No/NA
Operating manual and maintenance Instruction manual	Yes
Replacement parts availability list	Yes
Calibration certificates of all instruments	Yes
Material of Construction test certificate	Yes
Food grade certificate of rubber gasket	Yes
Test Certificates for Bought out items	Yes
Radiography test for weld joints	Yes
Factory Acceptance Test specification and test report	Yes
Installation and Operation Qualification protocol	Yes
Set and Reset point of all Field Instrument	Yes
As-built and As installed drawing	Yes
Wiring diagram of control panel	Yes
Cable Termination details of all field instruments	Yes
Documents required for PLC validation as written below (point no 5.4)	Yes

5.4 Following documents are required for PLC validation:

- Complete and accurate Process and Instrumentation Diagrams (P&IDs) with legend, which indicate all system components along with component tag numbers. The P&IDs provided by the supplier should include a cover sheet, which Indicates all symbols used to represent components and connections.
- A complete annotated input/output (I/O) listing (analog and digital), along with an application source code cross-reference indicating all software's used to program (e.g. relay logic, ladder logic, windows, C or Unix) PLC registers, timers, counters, used for developing a ladder logic for a particular operation including entire rung etc. In a ladder logic or any language which is used for control shall be shown on Drawing with clear demarcation for each sequential operation such as motor control, temperature control etc.
- Complete list of specifications (I/O List, etc.), purchase orders and manuals associated with computerized system for system automation including bought out items such as relays, enunciators, hooters, microprocessors, power supply units, earth relay units etc. Include copies of the current revisions within the Project Validation File. These documents are compiled for reference only.
- A complete and fully commented copy of the application source code (e.g., Ladder Logic) in hard copy showing an example to change the program sequence and set points and other process parameters as required by user through the three modes such as Maintenance, supervisor and operator level. Details for simulating the PLC without actual inputs should be shown clearly in a drawing. The facility of override the relays should be provided to test the integrity of each input for open and close loops.

- A PLC Control System architecture diagram, along with a complete hardware listing of the components supplied with the computer system (if not listed on the architecture diagrams).
- Complete list of communication cables directly interfacing with the PLC and I/O modules. Include cable number (tagging), start and ending terminals for the cables and associated drawing numbers.
- Entire cable schedule with termination details for each module (I/O) to be provided
- A description of operations, which describes all modes of operation (e.g., start-up, shutdown, manual/automatic) indicating all alarms with limits, actions, and responses.
- A complete description for restarting the system through PLC/DCS is to be submitted when the entire system goes to shutdown/power fail condition.
- Complete list of all Software related to the system. List the software name, purpose and version or date of revision. Include the storage location and media storage type used

6 PERFORMANCE SPECIFICATION

Dry Heat Sterilizer should be capable to

- Achieve 260°C and maintain for minimum 120 minutes with uniformity of temperature between 250 and 270°C within the chamber and load
- Reducer the spore count of *Bacillus subtilus* by more than 6 log.
- Reduce the endotoxin content in the load by more than 3 log

7 VALIDATION REQUIREMENT WITH SCOPE (WRITE YES OR NO AS REQUIRED)

Validation topic	Yes/ No	Scope
Design Qualification	Yes	User and Supplier
Installation Qualification	Yes	User and Supplier
Operational Qualification	Yes	User and Supplier
Performance Qualification	Yes	User
PLC validation	Yes	User
Any Other	No	Not applicable