



DESIGN QUALIFICATION PROTOCOL FOR DRY HEAT STERILIZER

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Approved By				



DESIGN QUALIFICATION PROTOCOL FOR DRY HEAT STERILIZER

1.0 Objective:

The purpose of Design Qualification of the Dry Heat Sterilizer is to ensure that all the critical aspects including safety, effective cleaning, maintenance, process requirements, utility requirement, product requirement, working space, assembling and dismantling of accessories have been considered while designing the equipment and they are properly documented.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	DRY HEAT STERILIZER
ID Number
Location	Media Preparation Room

3.0 Equipment / System Description:

Dry heat sterilizer shall be used for drying, sterilizing and depyrogenation of equipments, equipment parts, glassware and similar products. Loads will be placed over perforated shelves. Hot air is circulated through high temperature HEPA filter to ensure class 100 conditions. Chamber shall be double walled constructed with #13 gauges AISI 316L-2B stainless steel interior sheet.

4.0 Checklist for design verification:

Design of Dry heat sterilizer shall be verified for the compliance with the critical parameters mentioned in the URS/ executed tender.



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Size of chamber (mm)	600W x 700D x 1000H	600W x 700D x 1000H	
Volume of chamber	Not mentioned	420 LITRES	
Max operating temp	Not mentioned	250 DEG C (+/- 5)	
MOC of a. Internal contact parts. b. External non- contact parts.	SS316 L SS304	SS316 L SS304	
Insulation	Not mentioned	100 mm thick mineral wool	
HEPA filter	Not mentioned	0.3 micron	
Pre filter	Not mentioned	5 micron	
No of tray (removable)	Not mentioned	2 nos	
Validation port	Capable for at least 12 thermocouples or PT 100	50 mm dia with sanitary connection to insert flexible temperature probes of reqd. quantity.	
Damper	Not mentioned	Electrically actuated	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Blower a. Motor b. MOC	Not mentioned	a. TEFC motor, with insulation. b. SS304	
Pressure Gauges	Not mentioned	Magnehelic gauges-3 no. To monitor differential pressure inside the chamber and across HEPA filter.	
Control Panel 1.MOC 2. Control	Not mentioned	Stand alone unit SS304. It consist of fuses, relays, switches, PLC, Pilot Light, Printer Cabinet, MMI, Motor & PID Controller.	
Door opening Non-Sterile Side	Not mentioned	Door open Push Button Light for other side door status.	
Door opening Sterile Side	Not mentioned	Non-sterile side door open indicator Cycle ON, Cycle Completed indicator. Door Opening Push Button Unloading Acknowledgement push button.	
Surface Finish a) Internal Chamber b) External Chamber	----- Matt finish	≤ than 0.6 Ra Matt finish	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Heating System	Not mentioned	Electrical heater, SS rod type.	
Heater bank	Not mentioned	1 no. (27 KW)	
Printer	Not mentioned	Dot Matrix	
Model	Not mentioned	LX300	
Chamber temperature monitoring device	Not mentioned	6 point strip chart recorder	
Make	Yokogawa	Yokogawa	
PLC and MMI	Not mentioned	Three levels of password protection Control of 6 process files Provision of F0 calculation	
Make	Siemens	Siemens	
Alarms	Not mentioned	Alarms for all the critical parameters are provided.	
Utilities	Not mentioned	415 VAC, 50 Hz, 3 phase + neutral + earthing	



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5.0 Any Changes identified towards equipment design / lay out.

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6.0 Recommendations and Conclusions:

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7.0 References:

- User requirement specification.
- Copy of purchase order.
- Risk assessment.
- Design qualification / Document submitted by the supplier / vendor

8.0 Documents Attached:

Document Title	Annexure No.
List of changes / deviation	I
User requirement specification.	II
Copy of purchase order	III
Risk assessment	IV
Design qualification / Document submitted by the supplier / vendor	V



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9.0 Abbreviations:

URS	: User requirement specification
P.O.	: Purchase order
HEPA	: High efficiency particulate air
PLC	: Programmable logic controller.
MOC	: Material of construction
MMI	: Man machine interphase
mm	: Millimeter
SS	: Stainless Steel
⁰ C	: Degree centigrade



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Annexure - I

List of changes / Deviations

S.No.	Description of Change / Deviations	Justification

Verified By:

Approved By:



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Approved By				