INSTALLATION QUALIFICATION PROTOCOL FOR DRY HEAT STERILIZER

Pre - Execution Approval

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

INSTALLATION QUALIFICATION PROTOCOL FOR DRY HEAT STERILIZER

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Dry Heat Sterilizer is installed as per design.
- To ensure that the Dry Heat Sterilizer installed confirms to purchase specifications and manufacturer literature, and to document the information that the Autoclave meets the specification.

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 Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

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5.0 Checklist for Installation verification:

Installation of Dry Heat Sterilizer shall be verified for the compliance with the critical parameters mentioned in the Functional Design Specification.

The purpose of this checklist is to check and document the received material and installation at site with respect to drawings, details, and data sheets approved during DQ and GEP. GEP considers the basic engineering requirements for skilful maneuvering, means those methods and practices, which the administrator determines to be consistent with scientific and engineering principles.

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

……
……
……

8.0 References:

Purchase order (already available with Design Qualification)

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

10.0 Abbreviations:

IQ : Installation Qualification

DQ : Design Qualification

Post execution approval:

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

INSTALLATION QUALIFICATION PROTOCOL FOR DRY HEAT STERILIZER

Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	……..		
2.	Vendor's Name	Pharma lab Engineering		
3.	Instrument Make	Pharma lab		
4.	Instrument Model No.	……..		
5.	Design qualification Reference	Design qualification submitted by the vendor		
6.	Factory Acceptance Test (FAT) Certificate	Should be provided		
7.	Instrument Manual	Instrument Manual submitted by the vendor		

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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
1.	Size of chamber (mm)	Should be 600W x 700D x 1000H		
2.	Volume of chamber	Should be 420 Litres		
3.	MOC of Internal contact parts	Should be SS316 L		
4.	MOC of External Non- contact parts	Should be SS304		
5.	Insulation	Should be 100 mm thick mineral wool		
6.	HEPA filter	Should be of 0.3 micron		
7.	Pre filter	Should be of 5 micron		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
8.	No of tray (removable)	2 nos. Should be provided		
9.	Validation port	50 mm dia with sanitary connection to insert flexible temperature probes of reqd. quantity should be provided		
10.	Blower a. Motor b. MOC	a. TEFC motor, with insulation. b. SS304		
11.	Pressure Gauges	Magnehelic gauges - 3 no. To monitor differential pressure inside the chamber and across HEPA filter should be provided		
12.	Control Panel 1.MOC 2. Control	Stand alone unit SS304. It consist of fuses, relays, switches, PLC, Pilot Light, Printer Cabinet, MMI, Motor & PID Controller.		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
13.	Door opening Non-Sterile Side	Door open Push Button Light for other side door status should be provided		
14.	Door opening Sterile Side	Non-sterile side door open indicator Cycle ON, Cycle Completed indicator. Door Opening Push Button Unloading Acknowledgement push button		
15	Surface Finish a) Internal Chamber b) External Chamber	≤ than 0.6 Ra Matt finish should be provided		
16.	Heating System	Electrical heater, SS rod type should be provided		
17.	Heater bank	1 no. (27 KW) should be provided		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
18.	Printer	Dot Matrix printer should be provided.		
19.	Model	……..		
20.	Chamber temperature monitoring device	6 point strip chart recorder should be provided.		
21.	Make	Yokogawa		
22.	PLC and MMI	Three levels of password protection Control of 6 process files Provision of F0 calculation should be provided.		
23.	Make	Siemens		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
B.	**Location suitability**			
1.	Location	Should be place in Media Preparation Room		
C.	**Utilities**			
1.	Electrical Construction	415 VAC, 50 Hz, 3 phase + neutral + earthling should be provided		
D.	**Safety**			
1.	Alarm	Alarms for all the critical parameters should be provided.		
E.	MOC Certificates	Should be provided		
F.	Calibration Certificates	Should be provided		
G.	Testing Certificates	Should be provided		
H.	Drawing Details	Drawing No.		
1.	Drawing of Dry Heat Sterilizer	……		

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Annexure - III

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By:

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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

_____

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Summary Report Prepared By:

Date & Sign