INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

Pre - Execution Approval

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

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Autoclave is installed as per design.
- To ensure that the Autoclave 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	**AUTOCLAVE**
ID Number	**…….**
Location	**Media Preparation Room**

3.0 Equipment / System Description:

Autoclave shall be used for sterilization of clean room garments, disinfectant solutions, media for testing, quality control testing equipment accessories etc. Machine should meet all c GMP and GEP standards, and comply CE safety and electrical standards. Machine needs to run continuously in fully automatic mode. All control should be through PLC and operator friendly screen.

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.

5.0 Checklist for Installation verification:

Installation of Autoclave 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:

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……
……
……
……

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 HORIZONTAL AUTOCLAVE

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		

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
1.	Chamber size (H x W x D)	Should be 600 x 600 x 900 mm		
2.	Overall size (H x W x D)	Should be 1320x 2100 x 1200 mm		
3.	Capacity	Should be 324 Liter		
4.	Contact parts (MOC)	Should be SS 316 L		
5.	Non-contact parts (MOC)	Should be SS 304		
6.	Gasket	Food grade (Silicon & PTFE) & Temperature capacity 200ºC should be provided		
7.	Cladding	Should be Riveted cladded with SS 304		

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
8.	Insulation	Should be Glass wool insulation		
9.	Surface finish	Should be RA<0.8micron Matt / mirror finish		
10.	Validation Port	Capable of placing at least16 thermocouples		
11.	Temperature sensor	PT 100 sensor is located at the drain		
12.	Door type	Should be Double vertical sliding		
13.	PLC make	Should be of Siemens		
14.	Input for temperature and pressure	2 Analog input should be present for temperature and pressure		
15	Chart recorder	Should be Yokogawa make strip chart recorder		

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
16.	Safety valve for jacket and chamber	Safety valve should be present for jacket and pressure		
17.	Vent filter	Should be of 0.2 micron filter		
18.	Steam trap	Should be Located near the drain		
19.	Emergency stop switches	Should be Present on both sides sterile and non sterile side		
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		

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

S.No.	System Data	Acceptance Criteria	Actual	Remarks
D.	**Safety**			
1.	Alarm	Emergency off , Cycle over , Low pressure and low temperature alarm 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 Autoclave	……..		

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

Annexure - III

List of Changes / Deviations

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

Verified By:

Approved By:

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

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