



DESIGN QUALIFICATION PROTOCOL FOR AUTOCLAVE

Pre - Execution Approval

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



DESIGN QUALIFICATION PROTOCOL FOR AUTOCLAVE

1.0 Objective:

The purpose of Design Qualification of the Autoclave 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	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 design verification:

Design of Autoclave 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
Chamber size (HXWXD)	600 x 600 x 900 mm	600 x 600 x 900 mm	
Overall size (HXWXD)	Not mentioned	1320x 2100 x 1200 mm	
Capacity	Not mentioned	324 Litre	
Operation	Should be PLC operated	PLC operated	
Maximum Working temperature	Not mentioned	135°C	
Maximum Working Pressure	Not mentioned	2.1Kg/cm ²	
Design Pressure	Not mentioned	2.31Kg/cm ²	
Design temperature	Not mentioned	150°C	
Hydraulic test pressure	Not mentioned	Chamber - 3 Kg/cm ² Jacket - 3 Kg/cm ²	
MOC			
Contact parts	SS 316 L	SS 316 L	
Non-contact parts	SS 304	SS 304	
Gasket	Not mentioned	Food grade (Silicon & PTFE) Temperature capacity 200°C	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Insulation	Should be insulated with non-fiber shedding material	Glass wool insulation	
Surface finish	RA<0.8micron	RA<0.8micron Matt / mirror finish	
Cladding	Should be cladded with SS 304	Riveted cladded with SS 304	
Construction features	Machine should meet all cGMP and GEP standards, and comply CE safety and electrical standards	Machine meets all cGMP and GEP standards, and comply CE safety and electrical standards	
Validation Port	Should be capable of placing at least 16 thermocouples	Capable of placing at least 16 thermocouples	
Temperature sensor	PT 100 sensor should be provided at drain	PT 100 sensor is located at the drain	
Door type	Not mentioned	Double vertical sliding	
Operation mode	Pneumatically operated	Pneumatically operated	
Door interlocks	One door should be opened at a time	Door interlock is present to prevent simultaneous opening of both doors and to prevent the door opening during the process	
Door sealing criteria	Should be done by pressurized gasket sealing system	Door sealing is based on pressurized gasket sealing system	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Control system			
PLC make	Siemens	Siemens	
MMI	Should be provided	4 line display MMI for cycle selection and parameter setting	
Input for temperature and pressure	Not mentioned	2 Analog input is present for temperature and pressure	
Chart recorder	Should be of Yokogawa make	Yokogawa make strip chart recorder	
Safety valve for jacket and chamber	Not mentioned	Safety valve is present for jacket and pressure	
Printer	Should be of real time printing	Real time printer	
Password protection	3 level password control system should be provided	3 level password protection is present	
Vent filter	Not mentioned	0.2 micron filter	
Steam trap	Should be provided near the drain	Located near the drain	
Emergency stop switches	Should be provided on both sides	Present on both sides sterile and non sterile side	
Electrical Construction	440 VAC, 50 Hz, 3 phase	415 VAC, 50 Hz, 3 phase + neutral + earthling	
Alarm	Not mentioned	Emergency off , Cycle over , Low pressure and low temperature	



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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
cGMP	: current Good Manufacturing Practice
GEP	: Good engineering practices
CE	: Certificate of European compliance
RTD	: Resistance Temperature Detector
PLC	: Programmable logic controller.
MOC	: Material of construction
MMI	: Man machine interphase
mm	: millimeter
SS	: Stainless Steel
Kg	: Kilogram
°C	: Degree centigrade
cm	: Centimeter



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Annexure - I

List of changes / Deviations

S.No.	Description of Change / Deviations	Justification

Verified By:

Approved By:



DESIGN QUALIFICATION PROTOCOL FOR AUTOCLAVE

Post execution approval:

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