



**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE**

**Pre - Execution Approval**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



## INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE

### 1.0 Objective:

The purpose of installation qualification is as follows

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

### 2.0 Scope:

**Scope is limited to the following**

<b>Equipment / System Name</b>	<b>Vertical Autoclave</b>
<b>ID Number</b>	.....
<b>Location</b>	<b>Wash Room</b>

### 3.0 Equipment / System Description:

Vertical Autoclave is made of stainless steel, which is properly sealed to prevent it from leakage during the operation.

- The water immersion heater is fitted having total rating of 3500 watts to generate the steam at desired temperature and pressure.
- It is recommended to set 121°C to attain the steam pressure at 15 psi.
- The microprocessor controller ensures the accurate and precise result of desired test parameter.
- The samples are kept in the chamber using the carriers or baskets for sterilization at high degree of precise and even temperature throughout the cycle.
- The electronic timer pre-setted for pre fixed time duration of test cycle.
- The users at their options may use the sterilization indicator for confirmation of test.
- Vertical Autoclave shall be used to discard the used media.



**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE**

**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 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:**

- Copy of Purchase order
- 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
- Annexure - VII : Copy of Purchase order



**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE**

**10.0 Abbreviations:**

IQ : Installation Qualification

°C : Degree centigrade

**Post execution approval:**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL 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	Scientico Instruments		
3.	Instrument Make	Electron		
4.	Instrument Model No.	.....		
5.	Instrument Manual	Instrument Manual submitted by the vendor		



**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE**

**Annexure - II**

**Checklist for Installation Verification**

S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>A.</b>	<b>Equipment /Instrument specific details</b>			
1.	Vessel Dimensions (HXD)	Should be 710 x 450 mm		
2.	Vessel (MOC)	Should be SS - 304		
3.	Lid	Die pressed lid of 5 mm SS sheet with SS fly nut should be provided		
4.	Display	1. Dial gauge for Pressure indication. 2. LCD display for tem. , time & total process cycle should be provided		
5.	Heater	Ring type tubular immersion heater of 400 KW - 3/8 BSP threads should be provided.		
6.	Water low level sensor	Insulated SS probe fitted above heater should be provided		
7.	Validation Port	Provision of insertion of external scanner sensor		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>A.</b>	<b>Equipment /Instrument specific details</b>			
8.	Purging System	By Solenoid valve for auto purging initially & at the end of the cycle should be provided		
9.	Gasket	Should be of neoprene		
10.	Verification	Properly mounted, supported & connected		
		Properly labeled / identified		
		Major components are securely anchored and protected from shock		
		No observable physical damage		
		Electrical connections have been done according to drawing		
		Required electric connections are tight and proofed		
		Equipment identification nameplate is visible		



**PHARMA DEVILS**  
MICROBIOLOGY DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE**

S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>B.</b>	<b>Location suitability</b>			
1.	Location	Should be installed In Wash Room		
<b>C.</b>	<b>Utilities</b>			
1.	Electrical Power Supply	230 Volts AC 50Hz 1 phase supply should be provided		
<b>D.</b>	<b>Safety</b>			
1.	Safety Valve	1.First safety valve set at 15 psi. 2. Extra safety valve set at 20 psi		
<b>E.</b>	<b>MOC Certificates</b>			
1.	Not Applicable	Not Applicable		
<b>F.</b>	<b>Calibration Certificates</b>			
1.	Calibration Certificates	Should be provided		
<b>G.</b>	<b>Testing Certificates</b>			
1.	Testing Certificates	Should be provided		
<b>G.</b>	<b>Drawing Details</b>			
1.	Not Applicable	Not Applicable		





**INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL 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 VERTICAL AUTOCLAVE**

**Annexure - VI**

**Summary Report of Installation Qualification**

<b>Checks</b>	<b>Observations (Yes / No)</b>	<b>Reviewed By Sign / Date</b>
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**