



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
HIGH PRESSURE HIGH VACUUM  
STEAM STERILIZER  
SIZE: 750 x 750 x 1200 mm**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Unit Preparation Room</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE – APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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**2.0 OBJECTIVE:**

- To provide documented evidence for the Installation Qualification of HPHV Steam Sterilizer in Three Piece line.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

**3.0 SCOPE:**

- The scope of this installation qualification protocol cum report is limited to qualification of HPHV Steam Sterilizer in Three piece line, (**Make: MACHIN FABRIK**) to be installed in the **Unit Preparation Room** at .....
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Autoclave cum Bung Processor



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Approval of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Review of Performance Qualification Protocol.</li><li>• Analytical Support (Microbiological Testing/Analysis)</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none"><li>➤ GA Drawing.</li><li>➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.</li><li>➤ Details of utilities.</li><li>➤ Identification of components for calibration.</li><li>➤ Material of construction of all components.</li><li>➤ Brief Process Description.</li><li>➤ Safety Features and Alarms.</li></ul></li><li>• Post Approval of Qualification Protocol after Execution.</li></ul>



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	HPHV steam sterilizer
<b>Equipment ID.</b>	.....
<b>Manufacturer's Name</b>	Machin febrik
<b>Serial No.</b>	.....
<b>Supplier's Name</b>	Machin febrik
<b>Location of Installation</b>	Unit Preparation Room

**6.0 SYSTEM DESCRIPTION:**

**STANDARD STEAM STERILIZER:**

Standard steam sterilizer is a jacketed pressure vessel. The Standard Program cycle is initiated by introducing steam into the jacket. This essentially aids in preheating the chamber and effective utilization of heat energy.

The Standard Displacement Program process is made up of three phases:-

- Heat Up
- Sterilization Hold
- Exhaust (Cooling)

When the pressure inside the jacket is reached up to a particular set pressure, steam is introduced into the chamber & chamber Air pockets are removed through the chamber condensate line. This will ensure uniform steam distribution and penetration in the chamber. The equipment is provided with steam traps & air vent system in chamber condensate line to ensure maximum removal of air pockets and steam condensate along with some wet steam vapors.

As the chamber temperature reaches to set sterilization temperature, the control system then control's the chamber temperature till the end of sterilization time.

After the sterilization hold time is completed, steam from the chamber is exhausted to bring down the chamber pressure up to the set Process End Pressure (close to atmospheric pressure).

The sterile load is then unloaded in the sterile area.

The High Pressure High Vacuum Steam Sterilization cycle process is used to sterilize & dry the load.

The High Pressure High Vacuum Steam Sterilization cycle consists of following phases:-

- Vacuum Steam Pulsing
- Sterilization Hold
- Vacuum drying



## **INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

- Sterile Air In (Vacuum break)

This process is initiated by introducing steam into the jacket. This essentially aids in preheating the chamber and effective utilization of heat energy. In this process initially vacuum is created & then steam is introduced in the chamber up to the set value. These pulses are created 3 to 4 times to remove the air pockets.. The steam & vacuum pulsing not only ensures removal of air pockets and cold spots but also ensures uniform temperature distribution & penetration.

The vacuum is created with the help of water ring type vacuum pump.

After completion of fixed number of pulses, the chamber temperature reaches to set sterilization temperature. The control system then control's the chamber temperature till the end of sterilization time.

After the completion of sterilization time, vacuum up to a pre-determined level is created in the chamber. When this vacuum level is reached, the control system ensures that the vacuum is maintained for the specified time. The vacuum created at this stage ensures drying of the load inside the chamber.

After the completion of vacuum drying time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

The sterilized load is then unloaded from the chamber.

### **7.0 PRE – QUALIFICATION REQUIREMENTS:**

#### **7.1 Verification of Documents:**

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

#### **7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

#### **7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 PROCESS/PRODUCT PARAMETERS:**

<b>Installation Checks</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Grouting and Mounting</b>	Should be properly grouted and mounted.		
<b>Leveling</b>	Should be properly balanced and leveled.		
<b>Edges of parts</b>	Metal parts should be properly ground without any sharp edges.		
<b>Welding of Joints</b>	Welding of joints should be without any welding burrs.		
<b>Place of Installation</b>	Unit preparation Room 'I' Block.		
<b>Room Condition</b>	General Room Conditions.		
<b>Illumination</b>	NLT 300 Lux		
<b>Working space around the Equipment.</b>	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**Checked By  
(Production)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**

.....  
.....  
.....

**Reviewed By  
(Manager QA)  
Sign/Date: .....**





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

**8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Electricity	415 Volts AC $\pm$ 10%, 50 Hz Three Phase		
Light Indication for Machine Working Condition	Shall be properly connected and identified		
Plant Steam for Jacket	Pressure: 1.5 kg/cm <sup>2</sup>		
Pure Steam for chamber	Pressure: 1.2-1.4 kg/cm <sup>2</sup>		
Compressed Air	Pressure: 6-7 kg/cm <sup>2</sup>		
Soft Water for Vacuum System	1.2 kg/cm <sup>2</sup>		

**8.3 WORKING CONDITION AND TEST PARAMETER**

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
<b>Working (Chamber) Pressure</b>	2.2 kg/cm <sup>2</sup> (g)		
<b>Hydro test (Chamber) Pressure</b>	3.3 kg/cm <sup>2</sup> (g)		
<b>Working (Jacket) Pressure</b>	2.2 kg/cm <sup>2</sup> (g)		
<b>Hydro test (Jacket) Pressure</b>	4.4 kg/cm <sup>2</sup> (g)		



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**8.4 INSTALLATION CHECKS :**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>1.0 Shell design</b>			
<b>Chamber</b>			
Type	Rectangular		
Chamber Internal Size	750x750x1200		
Plate Thickness	6 mm		
Chamber Volume	675 Liters		
Material of construction	SS316L		
Finish	Ra ≤ 0.8 μm		
Working Pressure	2.2 kg/cm <sup>2</sup>		
Hydrotest Pressure	3.3 Kg/cm <sup>2</sup>		
Working temperature	Up to 134 <sup>0</sup> C		
<b>Jacket</b>			
Type	Full		
Plate Thickness	5 mm		
Material of construction	SS304		
hydro test pressure	4.4 kg/ cm <sup>2</sup>		
<b>Air Pocket</b>			
Plate Thickness	5 mm		
Material of construction	SS304		
pneumatic test pressure	4.5 kg/cm <sup>2</sup>		
<b>Shell Insulation</b>			
Insulation Material	Resin Bonded Glass wool		
Insulation Thickness	50 mm		
Insulation Skin Temperature	55° C (Subjected to room temperature 23 ± 2 <sup>0</sup> C)		
Insulation Cover Thickness	0.558 (24G)		
Insulation Cover material	SS304		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Stand</b>			
Stand material	SS304		
Thickness	40 x 40 (14 G)		
<b>Skid</b>			
Skid material	SS304		
Thickness	02 mm (14 G)		
<b>Rails &amp; Baffles</b>			
Material	SS316L		
Thickness	16 G		
<b>Validation Port with Dummy Adaptor</b>			
MOC	SS316		
No of probes arrangement in each port	8 Nos.		
Qty of port	2 Nos.		
<b>Port for Chamber Flexible RTD Sensor</b>			
MOC	SS 316		
No of Sensor	8 Nos.arrangement in each port		
Quantity	1 No.		
<b>Compound Gauge</b>			
<b>Jacket</b>			
Make	Forbes Marshall		
Type	Bourdon		
Mounting	Panel		
Range	1 To 6 kg/cm <sup>2</sup> (g)		
MOC	SS316 for Contact Part SS304 for Non Contact Part		
Accuracy	± 1% FS		
Connection	3/8" BSP, Back Connection		
Location	Loading Side		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Function	Indication of Jacket Pressure		
<b>Chamber</b>			
Make	Forbes Marshall		
Type	Bourdon		
Mounting	Panel		
Range	1 To 6 kg/cm <sup>2</sup> (g)		
MOC	SS316 for Contact Part SS304 for Non Contact Part		
Accuracy	± 1% FS		
Connection	3/8" BSP, Back Connection		
Location	Unloading and Loading Side		
Function	Indication Of Chamber pressure		
<b>2.0 DOOR &amp; DOOR COMPONENTS</b>			
<b>Door</b>			
Type	Vertical Sliding		
Quantity	2 Nos.		
Finish	Ra ≤ 0.8		
Material	SS316L (Only for Contact Part)		
Thickness	Door plate 14 mm		
<b>Door Insulation System</b>			
Insulation Material	Resin Bonded Glass wool		
Insulation Thickness	50 mm		
Insulation Outer Cover material	SS304		
Insulation Outer Cover material thickness	1.21 mm (18G)		
<b>Door Components</b>			
Door Components material	SS304		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Door Extension material	SS304		
<b>Door Gasket</b>			
Material	Food Grade Silicon		
Size	20 (OD) x 9 (ID) x 3535 (L) mm		
Working Temperature	134 °C		
Working Pressure	3 kg/cm <sup>2</sup> (g)		
Quantity	2 Nos.		
<b>Door Operating Cylinder (5A,5B)</b>			
Make	Aircon Pneumatic		
Mounting	Vertical		
Type	Telescopic		
Size	860 Stroke		
Quantity	2 Nos.		
Function	Door Operation.		
<b>Solenoid Valves for Door Operating Cylinder (501, 502 &amp; 503, 504,)</b>			
Make	Festo/ Janatics		
Type	JMFH - 5/4, Double coil		
Operating Pressure Range:	1.5 To 8.0 bar		
Coil Supply	1 PH – 230V – 50Hz		
Quantity	2 Nos.		
Function	To operate the door operating cylinder		
<b>Door Locking Cylinder (5C, 5D)</b>			
Make	JANATICS/Rotex		
Product	CS50118		
Mounting	Horizontal		
Type	Double Acting		
Size	40 Bore X 25 Stroke		



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Quantity	2 Nos.		
Function	To prevent accidental fall of door when it is in closed position.		
<b>Solenoid Valves for Door Locking Cylinder (509, 515, 510, 514)</b>			
Make	FESTO/Janatics		
Type	JMFH - 5 ¼, Double Coil		
Operating Pressure Range	1.5 to 8.0 bar		
Coil Supply	1 Phase, 230 V, 50 Hz		
Quantity	2 Nos.		
Function	To operate the door locking cylinder		
<b>Solenoid Valves for Gasket Pressurization/Retraction (505,506,507,508,511)</b>			
Make	Patcon		
Model	2 Way On/Off		
Coil Supply	1 Phase, 230 V, 50 Hz		
Quantity	5 Nos.		
Function	To pressurize and retract the gasket to facilitate the door opening and closing.		
<b>Regulator (5 J, 5K)</b>			
Make	Janatics/ Rotex		
Model	R 13614		
Size	¼" BSP		
Range	0.5 to 10 Bar		
Function	One is used for door operation & the other one is used for gasket pressurization		
<b>Filter Regulator Lubricator (5I)</b>			
Make	Janatics/ Rotex		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	FRC136134		
Size	¼" BSP		
Range	0.5 to 10 Bar		
Function	To filter, regulate & lubricate the incoming compressed air.		
<b>Pressure Switch (56,57)</b>			
Make	ORION		
Model	MG H04 KS 10		
Range	0.2 to 3.6 bar		
Accuracy	±1.5 % FSR		
Quantity	2 Nos.		
Function	To set the pressure level for the gasket on unloading and Loading side		
<b>Vacuum Switch (58,59)</b>			
Make	ORION		
Model	MG V00 KA10		
Range	760 mm to 100 mm of Hg (Vacuum)		
Accuracy	±2 % FSR		
Quantity	2 Nos.		
Function	To set the pressure level for the gasket on unloading and Loading side.		
<b>Ejector (55)</b>			
Make	FESTO		
Model	Vad ¼		
Size	¼" BSP		
Function	To retract door gasket before opening door.		
<b>Compound Gauges for NST Gasket Loading side (54)</b>			
Make	FORBES MARSHALL		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Type	Bourdon		
Mounting	Panel		
MOC	SS 316 L for Contact Part SS 304 for Non Contact Part		
Range	-1 To 6 kg/cm <sup>2</sup> (g)		
Quantity	1 Nos.		
Accuracy	± 1% FS		
Connection	3/8" BSP (M)		
Compound Gauge at	Loading side gasket pressure &		
Compound Gauge at unloading side	Unloading side gasket pressure		
Function	Indication of Loading gasket pressure.		
<b>Compound Gauges for NST Gasket Loading side &amp; unloading side (53A, 53B)</b>			
Make	FORBES MARSHALL		
Type	Bourdon		
Mounting	Panel		
MOC	SS 316 L for Contact Part SS 304 for Non Contact Part		
Range	-1 To 6 kg/cm <sup>2</sup> (g)		
Quantity	2 Nos.		
Accuracy	± 1% FS		
Connection	3/8" BSP (M)		
Compound Gauge at Loading side	Loading side gasket pressure & Unloading side gasket pressure.		
Compound Gauge at unloading side	Unloading side gasket pressure		
Function	Indication of Loading & Unloading gasket pressure.		





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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Limit Switch (5E, 5F, 5G, 5H)</b>			
Make	BOHMEN		
Model	1 NO + 1 NC		
Type	LSRS		
Quantity	4 Nos.		
Function	Sensing the door position		
<b>Photocell Sensor</b>			
Make	P & F/Optex		
Model	M5/MV5/32/115		
Type	Single Path		
Quantity	2 Sets		
Function	Door obstruction safety.		
<b>3.0 Panelling</b>			
Location of Paneling	On all four sides (As per layout)		
Paneling Finish	$Ra \leq 1.0$		
Mounting	On Skid		
Thickness	1.21 mm (18G)		
Material of panelling	SS304		
Contamination Seal Material	SS304 at Unloading Side		
<b>4.0 PROCESS CONTROL SYSTEM</b>			
<b>Piping</b>			
Piping Material	SS 316 L for Contact Part		
End Connection	Triclover		
Piping Material	SS 316 L for Non Contact Part		
End Connection	Threaded		
<b>Pneumatic Piston Type Valve with Solenoid (101,201,209,210,210A)</b>			
Make	Machinfabrik		



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Critical Variables	Acceptance Criteria			Observation	Observed By (Engineering) Sign/Date
MOC	SS 316 L				
Type	Single Acting				
End Connection	Threaded/ Triclover				
	Valve No.	Size	Function		
	101	½ BSP	Jacket Steam in		
	201	½ OD TC	Chamber Exhaust		
	209	½ OD TC	Chamber Condensate		
	210	½ OD TC	Chamber steam in		
	210A	½ OD TC	Chamber steam in (small)		
<b>Manual Ball Valve</b>					
Make	President				
Type	3PC Design				
End Connection	Triclover				
Valve no.	2210 A				
Size	½” OD TC (SS 316 L)				
Function	Chamber Steam In				
Valve no.	2201				
Size	½” BSP				
Function	Chamber Exhaust				
<b>Manual Needle Valve (2201)</b>					
Make	President SS304				
Type	3PC Design				
End Connection	Threaded				
Valve no.	2201				
Size	½” BSP				



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Function	Chamber Exhaust		
<b>Non Return Valve (29,2D)</b>			
Make	Leader		
MOC	Brass		
End Connection	Threaded		
Valve no.	29		
Size	½" BSP		
Function	to prevent backflow from the drain line to chamber		
<b>Safety Valve (10,20)</b>			
Make	Teleflo/Fainger Leser		
MOC	SS 304		
Type	Spring Loaded		
Range	0 to 3 kg/cm <sup>2</sup> (g)		
End Connection	Threaded		
	Valve No.	Size	Function
	10	¾" x ¾" BSP	To prevent the jacket from over pressure conditions
	20	¾" x ¾" BSP	To prevent the chamber from over pressure conditions
<b>Steam Trap (12,24)</b>			
Make	Spirax marshall		
Model	SOFT31-0		
Type	Float Type		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
MOC	Cast Iron with Brass Contact Parts		
End Connection	Threaded		
Valve no.	12		
Size	½” BSP		
Function	Jacket Condensate		
Valve no.	24		
Size	½” BSP		
Function	Jacket Condensate		
<b>Pressure Switch for jacket (17)</b>			
Make	Orion		
Range	0.2 to 3.6 bar		
Accuracy	± 1.5%FSR		
Qty.	01 Nos.		
Valve no.	17		
Model	MG H04 KS 10		
Function	To set pressure level of Jacket		
<b>Pressure Switch for Door gasket(56,57)</b>			
Make	Orion		
Range	0.2 to 3.6 bar		
Accuracy	± 1.5%FSR		
Qty.	02 Nos.		
Model	MG H04 KS 10		
Function	To set pressure level of gasket		
<b>Pressure Switch for door gasket (20M)</b>			
Make	ORION		
Model	MG LP KS 10		
Pressure housing MOC	SS 316		
Range	0.067 to 0.213 bar		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
End Connection	Threaded		
Valve No	20M		
Quantity	1 No.		
Function	To set pressure level of chamber		
<b>5.0 Vacuum System</b>			
<b>Vacuum pump &amp; motor</b>			
Make	New Genre/ PPI		
Type	LX-2		
Capacity	50 m3/hr		
Location	On Skid		
HP / RPM	3HP/ 2850 RPM		
Function :	To create vacuum in the chamber		
<b>Steam Condenser</b>			
Type	Shell & Tube		
Transfer area	0.24 m2		
Location	On Skid		
Material	Material : SS304		
Function	To condense the exhaust steam (from Chamber) before entering the vacuum pump.		
Hydrotest Pressure	Tube : 4.4 kg/cm <sup>2</sup> (g) Shell : 3.0 kg/cm <sup>2</sup> (g)		
<b>Pneumatic Piston Type valve</b>			
Make	MACHINFABRIK		
MOC	SS 316 L		
Type	Single Acting		
End Connection	Triclover/ Threaded		
	Valve No.	Size	Function



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Critical Variables	Acceptance Criteria			Observation	Observed By (Engineering) Sign/Date
	202	1" OD TC	Chamber vacuum		
	208	½"OD TC	Chamber filter air in		
	301	½" BSP	Vacuum Pump softened water in		
<b>Non Return Valve</b>					
Make	LEADER				
MOC	Brass				
End Connection	Threaded				
Valve no.	2D				
Size	1" BSP				
Function	To prevent backflow from vacuum pump to chamber				
<b>Air Filter</b>					
Make	SARTORIUS/PALL				
Filter Retention	0.2 micron				
End Connection	1 ½" OD TC				
Location	On Unloading Side.				
<b>Function</b>	To filter the air before entering into the Chamber				
<b>6.0 ELECTRICAL CONTROL PANEL &amp; POWER PANEL</b>					
Type	Inbuilt				
Material	SS304				
<b>Switch Gear</b>					
Contractor	SIEMENS				
Miniature Circuit Breaker	SIEMENS				
Over Load Relay	SIEMENS				



## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Indication Lamp	Techink/Mimic		
Terminal Block	Elmex /Connect well		
<b>Control Indication On Unloading Side</b>			
Push Buttons with indication lamps	Color coded push buttons with indication lamps are provided for the following: <ul style="list-style-type: none"><li>• Unloading door open.</li><li>• Unloading door close.</li><li>• Unloading door acknowledge.</li><li>• Emergency stop.</li></ul>		
Indication lamps	Color coded indication lamps are provided for the following: <ul style="list-style-type: none"><li>• Door precondition indication.</li><li>• Process on/end indication.</li></ul>		
<b>Control Indication On Loading Side</b>			
Push Buttons with indication lamps	Color coded push buttons with indication lamps are provided for the following: <ul style="list-style-type: none"><li>• Loading door open.</li><li>• Loading door close.</li><li>• Emergency stop.</li><li>• Control on/off switch.</li></ul> Heater on/off switch.		



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Indication lamps	Color coded indication lamps are provided for the following: <ul style="list-style-type: none"><li>• Door precondition indication.</li><li>• Alarm Indication.</li></ul>		
MMI	The operator interface (E 1061) is fitted onto the Control Panel.		
Printer	The Printer is fitted onto the Control Panel.		
Strip Chart Recorder	The Strip Chart Recorder is fitted onto the Control Panel.		

**7.0 INSTRUMENTATION**

**PLC**

Make	mitsubishi		
Model	FX1N 24MRES		
No. of digital inputs	14 Nos.		
No. of digital inputs used:	5 Nos.		
Type of input	24V DC		
No. of digital outputs	10 Nos.		
No. of digital outputs	10 Nos.		
Type of output	Potential Free Relay		
Function	To control the process automatically.		

**Extension Card (O/P Card)**

Make	mitsubishi		
Model	FX2N 8EYRES		
No. of digital Outputs	08Nos.		





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
No. of digital Outputs s used	01Nos.		
Type of Output	230 V AC		
Function	To add additional output to PLC.		
<b>Analog I/P Card</b>			
Make	mitsubishi		
Model	FX1N 2ADBD		
No. of analog inputs	02Nos.		
No. of analog inputs used	02Nos.		
Type of analog input	4 to 20 mA		
Quantity	1 No.		
Function	To give analog input to PLC.		
<b>Analog I/P Card</b>			
Make	mitsubishi		
Model	FX2N 4ADPT		
No. of analog inputs	04Nos.		
No. of analog inputs used	04Nos.		
Type of analog input	Pt 100		
Quantity	1 No.		
Function	To give analog input to PLC		
<b>MMI</b>			
Make	MITSUBISHI (BEIJER Electronics)		
Model	E 1061		
Printer Port	Rs 232		
Function	To start the process & display online parameters.		



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Printer</b>			
Make	EPSON		
Model	LX 310		
Function	To print online parameters		
<b>D.C. Source</b>			
Make	SHAVISON		
Model	G31- 60 - 24		
Type	SMPS		
I/P Voltage	230 V AC		
O/P Voltage	24 V DC, 2.5 A		
Function	To provide 24 V DC, 2.5 A supply to PLC.		
<b>Pressure Transmitter</b>			
Make	JUMO		
Model	404366/000		
Range	0 to 4 bar (A) [ -1 to 3 bar (g) ]		
Accuracy	0.25%		
O/P	4 to 20 mA DC		
End Connection	½" BSP		
Quantity	1 No.		
Function	To convert pressure input to 4 - 20 mA.		
<b>Temperature Transmitter</b>			
Make	RADIX		
Type	TX1HM		
Range	0 to 200°C		
Accuracy	± 0.1% of FS		
I/P	PT 100		
O/P	4 to 20 mA		



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Quantity	1 No		
Function	To convert pressure input to 4 - 20 mA		
<b>Temperature Sensor (Inside the chamber)</b>			
Make	RADIX		
Type	PT100/ Duplex/ 3 Wire/ Flexible		
Size	6 mm Tip Dia. X 2" Long		
Cable Length	5 Meter Long		
Accuracy	Class A		
Quantity	4 Nos.		
<b>Temperature Sensor (Chamber Condensate)</b>			
Make	RADIX		
Type	PT100/ Duplex/ 3 Wire/ Fixed		
Size	6 mm Tip Dia. X 4" Long		
Accuracy	Class A		
Quantity	2 Nos.		
<b>Temperature Indicator cum Controller</b>			
Make	RADIX		
Model	Prima 481		
No. of Set Point	Single		
Range	0 to 200°C		
Quantity	1 No		
Function	For manual operation in case of PLC failure.		
<b>Strip Chart Recorder</b>			
Make/Model	YOKOGAWA/436106-2		
No. of Channels	Six		
No. & Type of Inputs	5T + 1P		
Temperature Sensors	5 Nos., PT100, 3 Wire		



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Range	0 to 200 <sup>0</sup> C		
Pressure	1 No., 4 to 20 mA		
Range	-1 to 3 bar		

**8.0 Handling Accessories**

Carriage			
Type	Full		
Material	SS316L		
Qty	1 No		
Arrangement	Shelves		
Pattern	Perforated		
Layer	2 Nos. equispaced		
Qty	4 Nos.		

**9.0 Trolley**

Type	Full		
Material	SS304		
Qty	2 Nos.		

**Checked By**  
**(Engineering)**  
**Sign/Date:** \_\_\_\_\_

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** \_\_\_\_\_

**Inference:** \_\_\_\_\_  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** \_\_\_\_\_



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

**8.5 MATERIAL OF CONSTRUCTION:**

S.No.	Parts Name	Material of Construction	Certificate No.	Observation	Observed By (Engineering) (Sign & Date)
1.	Chamber	SS 316 L	B4992		
2.	Jacket	SS 304	A9906		
3.	Air Pocket	SS 304	A9906		
4.	Insulation Material	Resin Bonded Glasswool	AMB-6191		
5.	Stand	SS 304	A5346		
6.	Skid	SS 304	1964/15		
7.	Baffles	SS 316 L	2929/15		
8.	Door	SS 316 L	B6330		
9.	Door Insulation System	Resin Bonded Glasswool	AMB-6191		
10.	Door Components	SS 304	1404/15		
11.	Pneumatic Piston Type Valve with Solenoid	SS 316 L	25009,25014,25007 25051,24987, 25046,24752, 24950		
12.	Contamination Seal	SS 304	0002/15		
13.	PANELLING	<b>SS 304</b>	0002/15		
14.	PIPING	<b>SS 316L</b>	B2402, G3/12/046, D2/23/057, A6500		
15.	Manual Needle Valve	SS 304	TC/3498/PVI		
16.	Non Return Valve	Brass	B/2840/MF		
17.	Safety Valve	SS 304	6199 6211		
18.	Steam Trap	Cast Iron with Brass Contact Parts	335714/1/106500280		
19.	Steam Condenser	SS304	C/2840/MF		



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

S.No.	Parts Name	Material of Construction	Certificate No.	Observation	Observed By (Engineering) (Sign & Date)
20.	Carriage	SS316L	1915/15		
21.	Trolley	SS304	2040/15		

**Checked By**  
**(Engineering)**  
**Sign/Date:** \_\_\_\_\_

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** \_\_\_\_\_

**Inference:** \_\_\_\_\_  
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\_\_\_\_\_

**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** \_\_\_\_\_



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

**8.6 DRAWING VERIFICATION:**

REFERENCE ENGINEERING DRAWINGS	DRAWING No.	AVAILABLE [Y/N]	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Process Diagram			
Instrumentation Block Diagram			
G.A Drawing of Control Panel			
Pnematic Diagram			
Full Carriage			
Full Trolley			
Layout Drawing of HPHV			
Piping and Instrumentation Diagram for HPHV Sterilizer			
Wiring Drawing of C/P (Power CKT) HPHV			

Checked By  
(Engineering)  
Sign/Date: \_\_\_\_\_

Verified By  
(Quality Assurance)  
Sign/Date: \_\_\_\_\_

Inference: \_\_\_\_\_  
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Reviewed By  
(Manager QA)  
Sign/Date: \_\_\_\_\_



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER**

**8.7 VERIFICATION OF CERTIFICATES:**

S. No.	DESCRIPTION	CERTIFICATE No.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
1.	Chamber Dimension	A/2840/MF		
2.	M.O.C. Of Chamber	B4992		
3.	Hydro Test Of Chamber	01/2840/MF		
4.	Finish Of Chamber	LUM/2015/11/12		
5.	M.O.C. Of Jacket	A9906		
6.	Hydro Test Of Jacket	01/2840/MF		
7.	M.O.C. Of Air Poket	A9906		
8.	Pneumatic Test Of Air Pocket	02/2840/MF		
9.	M.O.C. Of Door Plate	B6330		
10.	Finish Of Door	LUM/2015/11/12		
11.	Door Components	1404/15		
12.	Door Gasket	TC No.: 217		
13.	Shell Insulation	TC No.: AMB-6191		
14.	Door Outer Cover	Report No.: 0002/15		
15.	Shell Insulation Cover	Report No.: A5349		
16.	Baffles	Report No.: A2929		
17.	M.O.C Of Mounting Stand	Report No.: A5346		
18.	M.O.C Of Skid	Report No.: 1964/15		
19.	M.O.C Of Contamination Seal	Report No.: 0002/15		
20.	Panelling	Report No.: 0002/15		
21.	Piping	Size	Certificate No.	
		2"OD	B2402	
		3/4" OD	G3/12/046	
		3/8"OD	D2/23/057	
		1/2" OD	A6500	
22.	Pressure Switch For Door Gasket	A15021019 A12110438		
23.	Pressure Switch For Jacket	A15051520		
24.	Pressure Switch For Chamber	A14072154		
25.	Vacuum Switch For Gasket	A15041350 A15041346		
26.	Pneumatic Piston Type Valve With Solenoid (101,201,209,210,210A,202,208,301	25009 25014 25007		





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S. No.	DESCRIPTION	CERTIFICATE No.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
		25051 24987 25046 24752 24950		
27.	Compound Gauge For Jacket on Loading Side	Sr. No.:0615PG4058		
28.	Compound Gauge For Chamber Unloading Side	0615PG4086		
29.	Compound Gauge For Chamber(Loading Side	0615PG4056		
30.	Compound Gauge For Door Gasket Unloading Side	0615PG4037		
31.	Compound Gauge For Door Gasket NST On Loading Side	0615PG4078		
32.	Compound Gauge For Door Gasket St On Loading Side	0615PG4007		
33.	Pressure Switch For Utility	Tc/A0 112210/2		
34.	Steam Trap For Jacket & Chamber	335714/1/106500280		
35.	Steam Condenser	C/2840/Mf		
36.	Door Operating Cylinder	4656.1 4656.2, 860 STROKE		
37.	Ejector	9394		
38.	Regulator	46751		
39.	Temperature Sensors	215020431 215025687		
40.	Temperature Sensors (Flexible)	215015528 215015530 215015541 215015551		
41.	D.C. Source	150601131		
42.	Temperature Indicator Cum Controller	315016523/ G31-60-24		
43.	Non Return Valve	D/2840/MF		
44.	Vacuum Pump & Motor	Ref. No. 7152		
45.	Safety Valve For Jacket& Chamber	6199,6211		
46.	Hydro Test For Steam Condenser	03/2201/MF		
47.	Filter Regulator Lubricator	TC No.: 51955		
48.	Programmable Logic Controller	D/2840/MF		



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S. No.	DESCRIPTION	CERTIFICATE No.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
49.	Strip Chart Recorder	S5R707686		
50.	Pressure Transmitter	0198848001014360078		
51.	Pressure Switch For Jacket	A15051520		
52.	Pressure Switch For Door Gasket	A15021019 A12110438		
53.	Pressure Switch For Chamber	A14072154		
54.	Vacuum Switch For Door Gasket	A15041350 A15041346		
55.	Temperature Transmitter	115008175		

**Checked By  
(Engineering)**  
Sign/Date: \_\_\_\_\_

**Verified By  
(Quality Assurance)**  
Sign/Date: \_\_\_\_\_

**Inference:** \_\_\_\_\_  
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**Reviewed By  
(Manager QA)**  
Sign/Date: \_\_\_\_\_



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

**8.8 SAFETY:**

Checks	Acceptance Criteria	Observation	Observed By Engineering (Sign/Date)
<b>Joints</b>	Welding of joints without any welding burrs.		
<b>Leveling and Balancing</b>	Equipment should be properly balanced & leveled.		
<b>Metal Parts</b>	All the metal parts should be properly grounded without any sharp Edges.		
<b>Electrical Wiring and Earthing</b>	Electrical Wiring should be as per Approved Drawings. Double External Earthing to Control Machine (Panel and Motors) and Operator should be provided.		
<b>Insulation of Electrical Wire</b>	All Electrical Wiring should be insulated.		
<b>Noise Level</b>	Below 80 db		
<b>Safety valves</b>	Protect chamber & Jacket from over pressure		
<b>Pressure Switches</b>	Protect chamber & Jacket from over pressure		
<b>Insulation to Jacket</b>	Prevent opening of Door under pressure		
<b>Emergency stop</b>	Stop all the mechanical function upon		
<b>Door Interlocking</b>	Both Doors should not open same time		
	Doors should not be open when process is "ON".		
<b>Door Obstruction Safety</b>	While the door is closing, the door should retract to open if obstructed by hand or by any other object.		

**Checked By**  
**(Engineering)**  
Sign/Date: \_\_\_\_\_

**Verified By**  
**(Quality Assurance)**  
Sign/Date: \_\_\_\_\_

**Inference:** \_\_\_\_\_

**Reviewed By**  
**(Manager QA)**  
Sign/Date: \_\_\_\_\_



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

**9.0 REFERENCES:**

**The Principle Reference is the following:**

- Master Validation Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.
- Specifications and Requirements as specified in PO and URS.
- Operating and service manual for High Pressure high vacuum steam sterilizer.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Process diagram.
- Instrumentation block diagram
- GA drawing
- Pneumatic diagram
- Full carriage
- Full carriage
- Layout drawing of HPHV
- P&ID .
- Any other relevant documents.
- Certificate of MOC
- Calibration certificates







**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

**16.0 ABBREVIATIONS:**

AC	:	Alternate Current
BSP	:	British Standard Pipe
CFR	:	Code of Federal Regulation
cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate
db	:	Decibel
IQ	:	Installation Qualification
GA	:	General Arrangement
HPHV	:	High Pressure High Vacuum
HDPE	:	High Density Poly Ethylene
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
ID	:	Inner Diameter
I/P	:	Input
Kg	:	Kilogram
MCB	:	Miniature Circuit Breaker
mm	:	Millimeter
HMI	:	Human Machine Interface
MOC	:	Material of Construction
NA	:	Not Applicable
NB	:	Nominal Bore
No.	:	Number
OD	:	Outer Diameter
O/P	:	Output
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
RPM	:	Revolution per Minute
RTD	:	Resistance Temperature Detector
SS	:	Stainless Steel



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

URS	:	User Requirement Specification
V	:	Volt
W	:	Width
D	:	Depth
H	:	Height
Press.	:	Pressure
Temp.	:	Temperature
TC	:	Triclover
DC	:	Direct current
AC	:	Alternate current
PLC	:	Programmable Logic Controller
°C	:	Degree Centigrade
&	:	And
FS	:	Full Scale
FSR	:	Full Scale Reading
BSP	:	British Standard for Pipe Threading
Min	:	Minute
Cm <sup>2</sup>	:	centimeter square
%	:	Percent
SMPS	:	Switch Mode Power Supply





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH  
VACUUM STEAM STERILIZER**

**17.0 PROTOCOL POST APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			