



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

PROTOCOL No.:

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

SIZE: 750 x 750 x 1200 mm

EQUIPMENT ID. No.	
LOCATION	Unit Preparation Room
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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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.
- 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 (**Make: MACHIN FABRIK**) to be installed in the **Unit Preparation Room**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of HPHV Steam sterilizer



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



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5.0 EQUIPMENT DETAILS:

Equipment Name	HPHV steam sterilizer
Equipment ID.	
Manufacturer's Name	
Serial No.	
Supplier's Name	
Location of Installation	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
- Sterile Air In (Vacuum break)



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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.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Unit preparation Room		
Room Condition	General Room Conditions.		
Illumination	NLT 300 Lux		
Working space around the Equipment.	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:



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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 ²		
Pure Steam for chamber	Pressure: 1.2-1.4 kg/cm ²		
Compressed Air	Pressure: 6-7 kg/cm ²		
Soft Water for Vacuum System	1.2 kg/cm ²		

8.3 WORKING CONDITION AND TEST PARAMETER:

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



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8.4 INSTALLATION CHECKS :

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
1.0 Shell design			
Chamber			
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 ²		
Hydrotest Pressure	3.3 Kg/cm ²		
Working temperature	Up to 134 ⁰ C		
Jacket			
Type	Full		
Plate Thickness	5 mm		
Material of construction	SS304		
hydro test pressure	4.4 kg/ cm2		
Air Pocket			
Plate Thickness	5 mm		
Material of construction	SS304		
pneumatic test pressure	4.5 kg/cm2		
Shell Insulation			
Insulation Material	Resin Bonded Glass wool		
Insulation Thickness	50 mm		
Insulation Skin Temperature	55° C (Subjected to room temperature 23 ± 2 ⁰ C)		
Insulation Cover Thickness	0.558 (24G)		
Insulation Cover material	SS304		
Stand			



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Stand material	SS304		
Thickness	40 x 40 (14 G)		
Skid			
Skid material	SS304		
Thickness	2 mm (14 G)		
Baffles			
Material	SS316L		
Thickness	16 G		
Rails			
Material	SS316L		
Thickness	25 mm dia		
Validation Port with Dummy Adaptor			
MOC	SS316		
No of probes arrangement in each port	8 Nos.		
Qty of port	2 Nos.		
Port for Chamber Flexible RTD Sensor			
MOC	SS 316		
No of Sensor	8 Nos.arrangement in each port		
Quantity	1 No.		
Compound Gauge			
Jacket			
Make	Forbes Marshall		
Type	Bourdon		
Mounting	Panel		
Range	-1 To 6 kg/cm ² (g)		
MOC	SS316 for Contact Part SS304 for Non Contact Part		
Accuracy	± 1% FS		
Connection	3/8" BSP, Back Connection		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Location	Loading Side		
Function	Indication of Jacket Pressure		
Chamber			
Make	Forbes Marshall		
Type	Bourdon		
Mounting	Panel		
Range	-1 To 6 kg/cm ² (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		
2.0 DOOR & DOOR COMPONENTS			
Door			
Type	Vertical Sliding		
Quantity	2 Nos.		
Finish	Ra ≤ 0.8		
Material	SS316L (Only for Contact Part)		
Thickness	Door plate 14 mm		
Shell Insulation System			
Insulation Material	Resin Bonded Glass wool		
Insulation Thickness	50 mm		
Door outer cover			
Material	SS304		
Insulation Outer Cover material thickness	1.21 mm (18G)		
Door Components			



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Door Components material	SS304		
Door Extension material	SS304		
Door Gasket			
Material	Food Grade Silicon		
Size	20 (OD) x 9 (ID) x 3535 (L) mm		
Working Temperature	134 °C		
Working Pressure	3 kg/cm ² (g)		
Quantity	2 Nos.		
Door Operating Cylinder (5A,5B)			
Make	Aircon Pneumatic		
Mounting	Vertical		
Type	Telescopic		
Size	860 Stroke		
Quantity	2 Nos.		
Function	Door Operation.		
Solenoid Valves for Door Operating Cylinder (501, 502 & 503, 504,)			
Make	Festo/ Janatics		
Type	JMFH - 5¼, 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		
Door Locking Cylinder (5C, 5D)			
Make	JANATICS/Rotex		
Product	CS50118		
Mounting	Horizontal		
Type	Double Acting		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Size	40 Bore X 25 Stroke		
Quantity	2 Nos.		
Function	To prevent accidental fall of door when it is in closed position.		
Solenoid Valves for Door Locking Cylinder (509, 515, 510, 514)			
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		
Solenoid Valves for Gasket Pressurization/Retraction (505,506,507,508,511)			
Make	Patcon		
Model	PC22CDMF		
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.		
Regulator (5 J, 5K)			
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		
Filter Regulator Lubricator (5I)			



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Make	Janatics/ Rotex		
Model	FRC136134		
Size	¼" BSP		
Range	0.5 to 10 Bar		
Function	To filter, regulate & lubricate the incoming compressed air.		
Pressure Switch for door gasket (56,57)			
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		
Vacuum Switch for door gasket (58,59)			
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.		
Ejector (55)			
Make	FESTO		
Model	Vad ¼		
Size	¼" BSP		
Function	To retract door gasket before opening door.		
Quantity	1 Nos.		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Compound Gauges for NST Gasket Loading side (54)			
Make	FORBES MARSHALL		
Type	Bourdon		
Mounting	Pannel		
MOC	SS 316 L for Contact Part SS 304 for Non Contact Part		
Range	-1 To 6 kg/cm ² (g)		
Quantity	1 Nos.		
Accuracy	± 1% FS		
Connection	3/8" BSP (M)		
Function	Indication of Loading gasket pressure.		
Compound Gauges for ST Gasket Loading side & unloading side (53A, 53B)			
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 ² (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.		
Limit Switch (5E, 5F, 5G, 5H)			



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Make	BOHMEN		
Model	1 NO + 1 NC		
Type	LSRS		
Quantity	4 Nos.		
Function	Sensing the door position		
Photocell Sensor			
Make	P & F		
Model	M5/MV5/32/115		
Type	Single Path		
Quantity	2 Sets		
Function	Door obstruction safety.		
3.0 Panelling			
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		
4.0 PROCESS CONTROL SYSTEM			
Piping			
Piping Material	SS 316 L for Contact Part		
End Connection	Triclover		
Piping Material	SS 316 L for Non Contact Part		
End Connection	Threaded		
Pneumatic Piston Type Valve with Solenoid (101,201,209,210,210A)			
Make	Machin fabrik		
MOC	SS 316 L		
Type	Single Acting		



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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)		
Manual Ball Valve					
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				
Manual Needle Valve (2201)					
Make	President SS304				
Type	3PC Design				
End Connection	Threaded				
Valve no.	2201				
Size	½” BSP				
Function	Chamber Exhaust				
Non Return Valve (29,2D)					



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Critical Variables	Acceptance Criteria			Observation	Observed By (Engineering) Sign/Date
Make	Leader				
MOC	Brass				
End Connection	Threaded				
Valve no.	29				
Size	½" BSP				
Function	to prevent backflow from the drain line to chamber				
Safety Valve for jacket, chamber (10,20)					
Make	Fainger Leser				
MOC	SS 316				
Type	Spring Loaded				
Range	0 to 3 kg/cm ² (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		
Steam Trap for jacket & chamber (12,24)					
Make	Forbes marshall				
Model	SOFT31-0				
Type	Float Type				
MOC	Cast Iron with Brass Contact Parts				
End Connection	Threaded				
Valve no.	12				



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Size	½” BSP		
Function	Jacket Condensate		
Valve no.	24		
Size	½” BSP		
Function	Jacket Condensate		
Pressure Switch for jacket (17)			
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		
Pressure Switch for Door gasket(56,57)			
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		
Pressure Switch for chamber (20M)			
Make	ORION		
Model	MG LP KS 10		
Pressure housing MOC	SS 316		
Range	0.067 to 0.213 bar		
End Connection	Threaded		
Valve No	20M		
Accuracy	± 1.5%FSR		
Quantity	1 No.		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Function	To set pressure level of chamber		
5.0 Vacuum System			
Vacuum pump & motor			
Make	New Genre		
Type	LX-2		
Capacity	50 m3/hr		
Location	On Skid		
HP / RPM	3HP/ 2850 RPM		
Function :	To create vacuum in the chamber		
Steam Condenser			
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 ² (g) Shell : 3.0 kg/cm ² (g)		
Pneumatic Piston Type valve			
Make	MACHINFABRIK		
MOC	SS 316 L		
Type	Single Acting		
End Connection	Triclover/ Threaded		
	Valve No.	Size	Function
	202	1" OD TC	Chamber vacuum
	208	½"OD TC	Chamber filter air in



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	301	½" BSP	Vacuum Pump softened water in		
Non Return Valve					
Make	LEADER				
MOC	Brass				
End Connection	Threaded				
Valve no.	2D				
Size	1" BSP				
Function	To prevent backflow from vacuum pump to chamber				
Air Filter					
Make	SARTORIUS/PALL				
Filter Retention	0.2 micron				
End Connection	1 ½" OD TC				
Location	On Unloading Side.				
Function	To filter the air before entering into the Chamber				
6.0 ELECTRICAL CONTROL PANEL & POWER PANEL					
Type	Inbuilt				
Material	SS304				
Switch Gear					
Contractor	SIEMENS				
Miniature Circuit Breaker	SIEMENS				
Over Load Relay	SIEMENS				
Indication Lamp	Techink/Mimic				
Terminal Block	Elmex /Connect well				
Control Indication On Unloading Side					



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Push Buttons with indication lamps	Color coded push buttons with indication lamps are provided for the following: <ul style="list-style-type: none"> • Unloading door open. • Unloading door close. • Unloading door acknowledge. • Emergency stop. 		
Indication lamps	Color coded indication lamps are provided for the following: <ul style="list-style-type: none"> • Door precondition indication. • Process on/end indication. 		
Control Indication On Loading Side			
Push Buttons with indication lamps	Color coded push buttons with indication lamps are provided for the following: <ul style="list-style-type: none"> • Loading door open. • Loading door close. • Emergency stop. • Control on/off switch. Heater on/off switch.		
Indication lamps	Color coded indication lamps are provided for the following: <ul style="list-style-type: none"> • Door precondition indication. • Alarm Indication. 		
MMI	The operator interface (E 1061) is fitted onto the Control Panel.		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
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.		
No. of digital Outputs s used	01Nos.		
Type of Output	230 V AC		
Function	To add additional output to PLC.		

Analog I/P Card

Make	MITSUBISHI		
Model	FX3G- 2ADBD		
No. of analog inputs	02Nos.		



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

PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
No. of analog inputs used	02Nos.		
Type of analog input	4 to 20 mA		
Quantity	1 No.		
Function	To give analog input to PLC.		
Analog I/P Card			
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		
MMI			
Make	MITSUBISHI (BEIJER Electronics)		
Model	E 1061		
Function	To start the process & display online parameters.		
Printer			
Make	EPSON		
Model	LX 310		
Function	To print online parameters		
D.C. Source			
Make	SHAVISON		
Model	G31- 60 - 24		
Type	SMPS		
I/P Voltage	230 V AC		



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

PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
O/P Voltage	24 V DC, 2.5 A		
Function	To provide 24 V DC, 2.5 A supply to PLC.		
Pressure Transmitter			
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.		
Temperature Transmitter			
Make	RADIX		
Type	TX1HM		
Range	0 to 200°C		
Accuracy	± 0.1% of FS		
I/P	PT 100		
O/P	4 to 20 mA		
Quantity	1 No		
Function	To convert pressure input to 4 - 20 mA		
Temperature Sensor (Inside the chamber)			
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.		



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

PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Temperature Sensor (Chamber Condensate)			
Make	RADIX		
Type	PT100/ Duplex/ 3 Wire/ Fixed		
Size	6 mm Tip Dia. X 4" Long		
Accuracy	Class A		
Quantity	2 Nos.		
Temperature Indicator cum Controller			
Make	RADIX		
Model	Prima 481		
No. of Set Point	Single		
Range	0 to 200 ⁰ C		
Quantity	1 No		
Function	For manual operation in case of PLC failure.		
Strip Chart Recorder			
Make/Model	YOKOGAWA/436106-2		
No. of Channels	Six		
No. & Type of Inputs	5T + 1P		
Temperature Sensors	5 Nos., PT100, 3 Wire		
Range	0 to 200 ⁰ C		
8.0 Handling Accessories			
Carriage			
Type	Full		
Material	SS316L		
Qty	1 No		
Arrangement	Shelves		
Pattern	Perforated		
Layer	2 Nos. equispaced		
Qty	4 Nos.		



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

PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
9.0 Trolley			
Type	Full		
Material	SS304		
Qty	2 Nos.		

**Checked By
(Engineering)
Sign/Date:** _____

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

Inference: _____

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

8.5 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material Of Construction	Certificate No.	Observation	Observed By (Engineering) (Sign & Date)



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

PROTOCOL No.:

S.No.	Parts Name	Material Of Construction	Certificate No.	Observation	Observed By (Engineering) (Sign & Date)
1.	Chamber	SS 316 L	B7039R		
2.	Jacket	SS 304	B7041R		
3.	Air Pocket	SS 304	B7041R		
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	G2/07/011		
9.	Shell Insulation System	Resin Bonded Glasswool	AMB-6191		
10.	Pneumatic Piston Type Valve with Solenoid	SS 316 L	2929/15		
11.	Contamination Seal	SS 304	A5351		
12.	Panelling	SS 304	A5351		
13.	Piping	SS 316L	2929/15		
14.	Manual Needle Valve	SS 304	TC/3550/PVI		
15.	Non Return Valve	Brass	B/2888		
16.	Steam Trap	Cast Iron with Brass Contact Parts	335714/1/1065002820		
17.	Steam Condenser	SS304	C/2888/MF		
18.	Carriage	SS316L	1915/15		
19.	Trolley	SS304	2040/15		



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

PROTOCOL No.:

Checked By
(Engineering)
Sign/Date: _____

Verified By
(Quality Assurance)
Sign/Date: _____

Inference: _____

Reviewed By
(Manager QA)
Sign/Date: _____

8.6 DRAWING VERIFICATION:

REFERENCE ENGINEERING DRAWINGS	DRAWING NO.	AVAILABLE [Y/N]	OBSERVED BY (ENGINEERING) (SIGN/DATE)
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**INSTALLATION QUALIFICATION PROTOCOL CUM
REPORT FOR
HIGH PRESSURE HIGH VACUUM STEAM
STERILIZER**

PROTOCOL No.:

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: _____

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

8.7 VERIFICATION OF CERTIFICATES:

DESCRIPTION	CERTIFICATE NO.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
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PHARMA DEVILS

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

PROTOCOL No.:

DESCRIPTION	CERTIFICATE NO.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
Chamber Dimension	A/2888/MF		
M.O.C. Of Chamber	B7039R		
Hydro Test Of Chamber	MF/A/2015		
Finish Of Chamber	LUM/2016/03/19		
M.O.C. Of Jacket	B7041R		
Hydro Test Of Jacket	MF/A/2015		
M.O.C. Of Air Poket	B7041R		
Pneumatic Test Of Air Pocket	MF/B/2015		
Finish Of Door	LUM/2016/03/19		
Door Components	1404/15		
Door Gasket	TC No.: 217		
Shell Insulation	AMB-6191		
Door Outer Cover	A5351		
Shell Insulation Cover	A5349		
Baffles	2929/15		
M.O.C Of Mounting Stand	A5346		
M.O.C Of Skid	1964/15		
M.O.C Of Contamination Seal	A5351		
Panelling	A5351		
Piping	Size	B2402	
	2"OD	B2402	
	3/4" OD	G3/12/046	
	3/8"OD	D2/23/057	
	1/2" OD	A6500	
Pneumatic Piston Type Valve With Solenoid (101,201,209,210,210A,202,208,301)	25737,24791,25738,25709,25764		
Manual ball valve	TC/3550/PVI		
Manual Needle valve	TC/3550/PVI		
Compound Gauge For Jacket on Loading Side	Sr. No.:0215PG1860		
Compound Gauge For Chamber Unloading Side	1115PG0682		
Compound Gauge For Chamber(Loading Side	1115PG07078		
Compound Gauge For Door Gasket Unloading Side	1115PG0684		



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

PROTOCOL No.:

DESCRIPTION	CERTIFICATE NO.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
Compound Gauge For Door Gasket NST On Loading Side	1115PG0689		
Compound Gauge For Door Gasket St On Loading Side	1115PG0716		
Non return valve	B/2888		
Safety valve for jacket	11009479		
Safety valve for chamber	11020151		
Solenoid valve for door operating & door locking cylinder	10410		
Solenoid valve for process valve	47244		
Solenoid valve for gasket	F/05/15		
Steam Trap For Jacket & Chamber	335714/1/1065002820		
Steam Condenser	C/2888/MF		
Door Operating Cylinder	4777		
Door Locking Cylinder	54275		
Ejector	9394		
Regulator	46751		
Temperature Sensors (Fixed)			
Temperature Sensors (Flexible)			
D.C. Source	151001094		
Temperature Indicator Cum Controller	315028485		
Programmable logical controller	D/2888		
MMI	D/2888		
Vacuum Pump & Motor	7299		
Hydro Test For Steam Condenser	MF/C2015		
Filter Regulator Lubricator	51955		
Strip Chart Recorder	S5RB08388		
Pressure Transmitter	0212361901015390076		
Pressure Switch For Jacket	A15070365		
Pressure Switch For Door Gasket	A15070373		



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

PROTOCOL No.:

DESCRIPTION	CERTIFICATE NO.	AVAILABLE YES/NO	OBSERVED BY (ENGINEERING) SIGN & DATE
	A15070367		
Pressure Switch For Chamber	A15061096		
Vacuum Switch For Door Gasket	A15101849 A15101852		
Temperature Transmitter	115014456		
Photocell sensor	800572		

**Checked By
(Engineering)
Sign/Date:** _____

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

Inference: _____

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

8.8 SAFETY:



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

PROTOCOL No.:

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

Checked By

Verified By



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

PROTOCOL No.:

(Engineering)

Sign/Date: _____

(Quality Assurance)

Sign/Date: _____

Inference: _____

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

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.



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

PROTOCOL No.:

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

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

PROTOCOL No.:

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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

PROTOCOL No.:

16.0 ABBREVIATIONS:

AC	:	Alternate Current
BSP	:	British Standard Pipe
CFR	:	Code of Federal Regulation
cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
GA	:	General Arrangement
H.P.H.V.	:	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
URS	:	User Requirement Specification
V	:	Volt



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

PROTOCOL No.:

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 ²	:	centimeter square
%	:	Percent
SMPS	:	Switch Mode Power Supply



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

PROTOCOL No.:

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)			