



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

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

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



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1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

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 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
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 Installation Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of the Installation Qualification 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.
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	HPHV Steam Sterilizer
Id Number
Make	Machine Fabric
Sr. No.
Chamber size	600 (w) x 600 (h) x 900 (d) mm
Chamber volume	324 liters
Working pressure	Upto 2.2 kg/cm ² (g)
Working temperature	Upto 134 ⁰ C
Location of Installation	Unit Preparation Room

6.0 SYSTEM DESCRIPTION:

- The Sterilizer manufactured by **M/s. Machinfabrik Industries Pvt. Ltd.**, is designed for the best possible adaptation to the needs of the customer.
- The High Pressure High Vacuum Sterilizer has been an unique Sterilization System offered by **M/s. Machinfabrik Industries Pvt. Ltd.**, as it can be efficiently used to perform two types of sterilization processes; viz-
 - **Standard Program**
 - **HPHV**

The identification for any leakage & penetration of steam can be tested by the following methods:

- A) **Chamber Leak Test (Cold)**
- B) **Chamber Leak Test (Hot)**
- C) **Warm up Cycle**
- D) **Bowie Dick Test**

- As the name suggests the above two processes achieve sterilization with the help of Steam.

STANDARD STEAM STERILIZER:

Standard Program 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.



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

- a. Heat Up
- b. Sterilization Hold
- c. 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.

HIGH PRESSURE HIGH VACUUM STEAM STERILIZATION:

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 viz:-

- a. Vacuum Steam Pulsing
- b. Heat up
- c. Sterilization Hold
- d. Vacuum drying
- e. 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. Almost 95% removal of air is ensured from chamber. 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.



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After completion of fixed no. 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 –ve pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

The sterilized load is then unloaded from the chamber.

A. VACUUM LEAK TEST (COLD) :

- In this process initially vacuum is created up to the set level. Then it will hold as per the given delay hold time to settle down the vacuum in chamber, after that actual vacuum hold time will start (as per mention in HTM 2010 guideline) to know the chamber leakage. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

B. VACUUM LEAK TEST (HOT) :

- 1) In this process steam is introduced into the jacket, this preheats the chamber. After that vacuum is created & then steam is introduced in the chamber upto set value, these pulses are repeated 3 to 4 times to remove air pockets. In heat up, exhaust & steam pulses is repeated to for uniform temperature distribution & protection.
- 2) After completion of fixed no. of pulses the chamber temperature reaches to set sterilization temperature. The control system then control the chamber temperature tills the end of sterilization time.
- 3) After the sterilization chamber vacuum valve open to create vacuum & help in drying.
- 4) Then it will hold as per the given delay hold time to settle down the vacuum in chamber, after that actual vacuum hold time will start (as per mention in HTM 2010 guideline) to know the chamber leakage. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

C. WARM UP CYCLE:

- 1) In this process steam is introduced into the jacket, this preheats the chamber. After that vacuum is



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created & then steam is introduced in the chamber upto set value.

- 2) After completion of vacuum pulses the chamber temperature reaches to set Warm temperature. The control system then control the chamber temperature tills the end of Warm hold time.
- 3) After the Warm hold chamber vacuum valve open to create vacuum & vacuum hold start. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

D. BOWIE DICK TEST :

- 1) In this process steam is introduced into the jacket, this preheats the chamber after that vacuum is created & then steam is introduced in the chamber upto set value, these pulses are repeated 3 to 4 times to remove air pockets. In heat up exhaust & steam pulses is repeated to for uniform temperature distribution & protection.
- 2) After completion of fixed no. of pulses the chamber temperature reaches to set sterilization temperature. The control system then control the chamber temperature tills the end of sterilization time.
- 3) After the sterilization, Positive pressure in chamber is brought to atmospheric pressure by opening chamber exhaust valve.

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 (Complies/Not Complies)	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 'L' Block.		
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:

Critical variables	Acceptance criteria			Observation (Complies Non Complies)
	Pure Steam for Chamber	Compressed Air	Softened Water For Vacuum System	
Peak Demand	0.58 kg/min	0.2 m ³ /hr	7 lpm for 35 min cycle	
Cycle Demand	17.28 kg/cycle	--	--	
Pressure	1.2 – 1.4 kg/cm ² (g)	6-7 kg/cm ² (g)	1.2 kg/cm ² (g)	
Quality	Dry & Saturated	Lubricated & Moisture free	Softened Water, less than 25 ⁰ C	
Line Size	¾" OD	½" NB	½" NB	
End Connection	Triclover	Triclover	Triclover	

Checked By
(Production)

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:.....

Inference:

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

Reviewed By

(Manager QA)

Sign/Date:



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8.3 WORKING CONDITION AND TEST PARAMETER:

	Chamber	Jacket	Condenser		Air Pocket	Observation (Complies/Not Complies)
			Shell	Tube		
Working Pressure	2.2 kg/cm ² (g)	2.2 kg/cm ² (g)	1.5 kg/cm ² (g)	2.2 kg/cm ² (g)	3.0 kg/cm ² (g)	
Hydro test pressure	3.3 kg/cm ² (g)	4.4 kg/cm ² (g)	3.0 kg/cm ² (g)	4.4 kg/cm ² (g)	NA	
Working Temperature	134 ⁰ C	134 ⁰ C	NA	134 ⁰ C	60 ⁰ C	
Vacuum	Full	NA	NA	Full	Partial	
Pneumatic Test pressure	NA	NA	NA	NA	4.5 kg/cm ² (g)	

Checked By
(Production)

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date.....

Inference:

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

Reviewed By
(Manager QA)

Sign/Date:



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8.4 INSTALLATION CHECKS :

Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
SIZE				
Width	600 mm	A/3213/MF		
Height	600 mm			
Depth	900 mm			
Chamber				
MOC	SS 316L	I7635		
Thickness	6 mm			
Hydro-test pressure	3.3 kg/cm ² (g)	01/3213/MF		
Finish	Ra ≤ 0.8 μm	MF/3213/2017		
Jacket				
MOC	SS304	I7970		
Thickness	5 mm			
Type	Full	01/3213/MF		
Hydro-Test Pressure	4.4 kg/cm ² (g)			
Air Pocket				
MOC	SS304	I7970		
Thickness	5 mm			
Pneumatic Test Pressure	4.5 kg/cm ² (g)	02/3213/MF		
Door				
Number Of Doors	Two	I7634		
Door Design	Vertical Sliding			
Thickness	DOOR PLATE 14 mm – SS 316L (Only for Contact Part)			
Finish	Ra ≤ 0.8 μm	MF/3213/2017		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
Door Components				
Locking Member	SS 304	1964/16		
Door Gasket				
Material	Food Grade Silicon	343		
Size	20 (OD) X 9 (ID) X 2335 (L) mm			
Working temperature	134 ⁰ C			
Working pressure	3 kg/cm ² (g)			
Quantity	2 Nos.			
Shell Insulation				
Material	Resin Bonded Glass Wool	AMB-25891		
Thickness	50 mm			
Door Outer Cover				
Material	SS 304	I7507		
Thickness	1.21 mm (18G)			
Shell Insulation Cover				
Material	SS 304	P5134		
Thickness	0.558 mm (24G)			
Baffles				
Material	SS 316L	I7506		
Thickness	16G			
Stand				
Material	SS 304	D4734		
Thickness	40X40X(14G)			
Skid				
Material	SS 304	D2585		
Thickness	2 mm (14G)			



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
Contamination Seal				
Material	SS 304	I7507		
Thickness	1.21 mm (18G)			
Paneling				
Material	SS 304	I7507		
Thickness	1.21 mm (18G)			
Piping				
Material	SS 316L	Report No.:H1216 Dtd.: 08/02/2017.		
Size	2 ‘‘ OD x 16 G			
Size	1’’ OD X 16 G	Report No.:H1215 Dtd.:08/02/2017.		
Size	1’’ OD X 16 G	Report No.:H1210 Dtd.:08/02/2017.		
Size	¾’’ OD X 16 G	Certificate No.:H1207 Dtd.:08/02/2017.		
Size	½’’ OD X 16G	Certificate No.:E6768 Dtd.:14/02/2016.		
Size	3/8’’ NB X 16 Sch	Report No.: E6768 Dtd.:05/06/2016.		
Pneumatic Piston Type Valve With Solenoid (101, 201, 202, 208, 209 , 301)				
Make	Machinfabrik	SR. NO.: 30952,30957, 301004,		
Material of construction	SS 316L			
Type	Single acting			
End Connection	Threaded/ Plain End			
Size	¾’’ OD			
Quantity	3 Nos.			
Size	½’’ BSP	SR. NO.: 30601,31371.		
Quantity	2 NOS.			
Size	1’’ OD	SR. NO.: 31298.		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
Quantity	1 No.			
Proportionate Pneumatic Piston Type Valve (210)				
Make	Gemu	Sr. No. 55420D5934511R 1259		
Material of construction	SS 316L			
End Connection	Plain End			
Size	¾" OD TC (20NB)			
Quantity	1 No.			
Manual Needle Valve (2201)				
Make	PRESIDENT	TC NO.:TC/4251-B/PVI		
Material of construction	SS 304			
Size	½" BSP (15NB)			
End connection	Threaded			
Quantity	1 No.			
COMPOUND GAUGE FOR JACKET (1L)				
Make	Forbes Marshall	SR. NO.: 4H17043549		
Range	-1 TO 6 Kg/cm ² (g)			
Mounting	Panel			
Moc	SS316L for Contact Part SS304 for Non Contact Part			
Accuracy	± 1% FS			
Type	Bourdon			
Connection	3/8" BSP (M)			
Location	Loading Side			
Quantity	1 No.			
COMPOUND GAUGE FOR CHAMBER (UNLOADING & LOADING SIDE) (2C, 2C1)				
MAKE	FORBES MARSHALL	SR. NO.: 4H17036042		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
Range	-1 TO 6 Kg/cm ² (g)	4H17036044		
Mounting	Panel			
MOC	SS316L for Contact Part SS304 for Non Contact Part			
Accuracy	± 1% FS			
Type	Bourdon			
Connection	3/8" BSP (M)			
Location	Unloading And Loading Side			
Quantity	2 Nos.			

COMPOUND GAUGE FOR DOOR GASKET (LOADING SIDE) (54)

MAKE	Forbes marshall	SR. NO.: 4H17043557		
MOUNTING	Panel			
MOC	SS316L for Contact Part SS304 for Non Contact Part			
RANGE	-1 TO 6 Kg/cm ² (g)			
ACCURACY	± 1% FS			
TYPE	Bourdon			
CONNECTIO N	3/8" BSP (M)			
QUANTITY	1 No.			

COMPOUND GAUGE FOR GASKET (UNLOADING & LOADING SIDE) (53A, 53B)

MAKE	FORBES MARSHALL	SR. NO.: 4H17035966 4H17036054		
MOUNTING	PANEL			
RANGE	-1 TO 6 Kg/cm ² (g)			
MOC	SS316L for Contact Part SS304 for Non Contact Part			
ACCURACY	± 1% FS			
TYPE	BOURDON			



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
CONNECTIO N	3/8" BSP (M)			
QUANTITY	2 Nos.			
NON RETURN VALVE (29,2D)				
Make	LEADER	F/3213/MF		
Moc	BRASS			
End Connection	THREADED			
Size	½" BSP			
Quantity	1 No.			
Size	1" BSP			
SAFETY VALVE FOR JACKET,CHAMBER (10,20)				
MAKE	FAINGER LESER	SR. NO.: 11296933 11296928		
MOC	SS 316			
TYPE	SPRING LOADED			
SIZE	¾" BSP			
RANGE	0 TO 3 kg/cm ² (g)			
End connection	THREADED			
Quantity	2 Nos.			
AIR FILTER (AF)				
MAKE	SARTORIUS			
RETENTION	0.2 MICRON			
END CONNECTIO N	1½" OD TC			
QUANTITY	1 No.			
STEAM TRAP FOR JACKET AND CHAMBER (12,24)				
Make	Forbes marshall	TC NO.: 619677\ 5 \558505868		
Model	Soft31-o			
Type	Float type			



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
Material of construction	Cast iron			
Size	½” Bsp (15nb)			
End connection	Threaded			
Quantity	2 nos.			
VACUUM PUMP & MOTOR (VP)				
Make	NEW GENRE	M/C NO.: 8626		
Model	LX-2			
Type	WATERING TYPE			
Capacity	50 m ³ /hr			
Hp/rpm	3 HP/ 2850 RPM			
Quantity	1 No.			
STEAM CONDENSER (CI)				
Material	SS 304	B/3213/MF Dtd.:13/10/2017.		
Type	SHELL AND TUBE			
Transfer area	0.24 m ²			
Hydrotest pressure	TUBE : 4.4 kg/cm ² (g) SHELL : 3.0 kg/cm ² (g)	01/3213/MF Dtd.: 27/09/2017.		
DOOR OPERATING CYLINDER (5A,5B)				
Make	Janatics	TC NO.:87659		
Type	Double Acting			
Product No.	A240637100			
Mounting	Vertical			
Size	63 bore x710 STROKE			
Quantity	2 Nos.			
DOOR LOCKING CYLINDER (5C,5D)				



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
Make	Janatics	TC NO.: 87657		
Product no.	CS50118			
Mounting	Horizontal			
Type	Double acting			
Size	40 bore x 25 stroke			
Quantity	2 nos.			
SOLENOID VALVE FOR DOOR OPERATING & LOCKING CYLINDER (DOUBLE COIL) (501,502 & 503,504,509,515 & 510,514)				
Make	FESTO	PART NO.:10410		
Product type	JMFH-5-1/4			
Size	1/4"			
Range	1.5 To 8.0 Bar			
Quantity	4 Nos.			
SOLENOID VALVE FOR PROCESS VALVES (SINGLE COIL)				
Make	JANATICS	TC NO.:72551		
Product no.	E24002A			
Size	1/8"			
Quantity	7 Nos.			
FILTER REGULATOR LUBRICATOR (5I)				
MAKE	JANATICS	TC NO.:85003		
PRODUCT NO.	FRC136134			
SIZE	1/4" BSP			
PRESSURE CONTROL RANGE	0.5 To 10 Bar			
QUANTITY	1 No.			
SOLENOID VALVES FOR GASKET (505,506,507,508,511)				
MAKE	PATCON	BATCH		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
MODEL	PC22CDMF	NO.:1/12/17		
COIL SUPPLY	1PH – 230V – 50Hz			
QUANTITY	5 Nos.			
REGULATOR (5J,5K)				
Make	Janatics	TC NO.:46755		
Product no.	R 13614			
Size	¼“ BSP			
Pressure control range	0.5 To 10 Bar			
Quantity	2 Nos.			
EJECTOR (55)				
MAKE	FESTO	PART NO.:9394		
PRODUCT TYPE	VAD ¼”			
SIZE	¼” BSP			
QUANTITY	1 No.			
D.C. SOURCE				
MAKE	SHAVISON	SR. NO.: 170601776		
MODEL	G31-60-24			
TYPE	SMPS			
OUTPUT	24 VDC, 2.5 A			
INPUT	230 VAC			
QUANTITY	1 No.			
TEMPERATURE SENSORS (FIXED)				
MAKE	Radix	SR. NO.: 217032136		
TYPE	PT100 / DUPLEX /3 WIRE/ FIXED			



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
ACCURACY	CLASS A			
SIZE	6 mm TIP DIA X 4” LONG			
QUANTITY	1 No.			
TEMPERATURE SENSORS (FLEXIBLE)				
MAKE	RADIX	SR. NO.:		
TYPE	PT100 / DUPLEX /3 WIRE/ FLEXIBLE	217036079		
ACCURACY	CLASS A	217036102		
SIZE	6 mm TIP DIA X 2” LONG	217036082		
CABLE LENGHT	5 METER LONG	217036074		
QUANTITY	4 Nos.			
CONTROL SYSTEM				
PROGRAMMABLE LOGIC CONTROLLER				
Make	mitsubishi	C/3213/MF		
Model	FX3U 32MRES	Dtd.:13/10/2017.		
Analog i/p card	FX3U 3A ADP, FX3U 4ADPTW ADP			
Communication card	FX3U 485BD			
OPERATOR INTERFACE (MMI)				
MAKE	MITSUBISHI (Beijer Electronics)	C/3213/MF		
MODEL	E 1061	Dtd.:13/10/2017.		
QUANTITY	1 No.			
PASSWORD PROTECTION				
DESIGN	Password Protection To Set Parameters	NA		
FACTORY SETTING	3123			
PRESSURE TRANSMITTER (2E)				
MAKE	JUMO	SR. NO.:		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
MODEL	404366/000	023819760101732 0060		
RANGE	0 To 4 bar (A) {-1 to 3 bar(g)}			
OUTPUT	4 – 20 mA			
END CONNECTION	½” BSP			
QUANTITY	1 No.			

PRESSURE SWITCH FOR CHAMBER (20M)

Make	ORION	SR. NO.: A17061813		
Model	MG LP KS 10			
Pressure housing moc	SS 316L			
Range	0.067 To 0.213 Bar			
End connection	THREADED			
Accuracy	± 1.5% FSR			
Quantity	1 No.			

PRESSURE SWITCH FOR JACKET (17)

MAKE	ORION	SR. NO.: A17050346		
MODEL	MG H04 KS 10			
PRESSURE HOUSING MOC	SS 316			
RANGE	0.2 To 3.6 bar			
End connection	Threaded			
Quantity	1 No.			

PRESSURE SWITCH FOR DOOR GASKET (56,57)

MAKE	ORION	SR. NO.: A17080113		
MODEL	MG H04 KS 10			
RANGE	0.2 To 3.6 Bar	A17080101		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
QUANTITY	2 Nos.			
PRESSURE SWITCH FOR COMPRESSED AIR (3I)				
Make	ORION	SR. NO.: A17050389		
Model	MG H10 KS 10			
Range	0.5 To 10. Bar			
Quantity	2 Nos.			
End Connection	Threaded			
PRESSURE SWITCH FOR (softened Water & Plant Steam 30S & 3G) & (Pure Steam 3L)				
Make	Orion	Sr. No. A17022501 A17080957		
Model	MG H07 KS 10			
Pressure Housing MOC	SS316			
Range	0.5 to 7.0 Bar			
Qty	2 Nos			
Model	MGHO7KT BO	Sr. No. A17022059		
Qty	1 Nos			
VACUUM SWITCH FOR DOOR GASKET (58,59)				
Make	ORION	SR. NO.: A17062257 A17062266		
Model	MG V00 KA10			
Range	760 mm To 100 mm of Hg (Vacuum)			
Accuracy	± 2 % FSR			
Quantity	2 Nos.			
PRINTER				
TEMPERATURE TRANSMITTER				
MAKE	RADIX	SR. NO.: 117007868		
TYPE	TX1HM			
RANGE	0 To 200°C			



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
ACCURACY	± 0.1% of FS			
OUTPUT	4 – 20 mA			
INPUT	Pt 100			
QUANTITY	1 No.			
LIMIT SWITCH (5E, 5F, 5G, 5H)				
MAKE	BOHMEN	TC NO.: 197		
MODEL	1 NO + 1 NC			
TYPE	MLRLS			
QUANTITY	4 Nos.			
Validation Port with Dummy adapter				
MOC	SS	E/3213/MF		
No of Probe per Port	8 Nos			
Qty	2 Nos			
PHOTOCELL SENSOR				
MAKE	P & F	PART NO.:214745		
TYPE	SINGLE PATH			
MODEL	M100/MV100-RT/76a/103/115			
QUANTITY	2 SETS			
STRIP CHART RECORDER				
Make	YOKOGAWA	SR. NO.: S5T806786		
Model	436106-2			
No. Of channels	6			
Range	0 To 200 ⁰ C			
Quantity	1 No.			
VALIDATION PORT WITH DUMMY ADAPTOR				
Material	SS 316	E/3213/MF		



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Critical Variable	Acceptance Criteria	Sr/Certificate No.:	Observation (Complies/ Not Complies).	Observed By (Engineering) (Sign/Date)
No. Of probes per port	8 Nos.	Dtd.:13/10/2017.		
Quantity	2 Nos.			
Printer				
Make	Epson	D/3213/MF		
Model	LX310			
Qty	1 Nos			
Photocell Sensor				
Make	P & F	Part No.: 214745		
Type	Single Path			
Model	M100/MW 100-RT/76a/103/115			
Qty	2 Sets			
Shelves				
Type	Half	Report No.: D4739		
Material	SS316 L			
Pattern	Perforated			
Layer	2 Nos Equipspaced			
Qty	4 Nos			

Checked By (Production)

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:.....

Inference:

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Reviewed By (Manager QA)

Sign/Date:



INSALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

8.5 SAFETY FEATURES & ALARMS:

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	Observation Complies/Non Complies
Doors Inter Locks	<ul style="list-style-type: none"> • The two doors are interlocked electrically, that prevents both the doors from opening simultaneously. • When the process is on, the door is locked electrically and this prevents the door opening when the process is ON. • To start the process, the door close positions (for both doors) act as preconditions for the process. • Unloading side door will open only after satisfactory completion of the sterilization process. 	
Door Obstruction Safety	While the door is closing, the door till retract to open if obstructed by hand or any other object.	
Door/ Gasket Operation	Electro pneumatic	
Door Locking System	Pneumatic through process.	
Alarms	<p>Alarms will be on if</p> <ul style="list-style-type: none"> • Vacuum leak test failed. • Temperature overshoots. • Sterilization stops temperature. • Sterilization resets temperature. • Chamber pressure high. • Too long time for pre vacuum. • Too long time for pre pressure. • To long time heat up. 	



INSALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	Observation Complies/Non Complies
	<ul style="list-style-type: none">• Too long time for post vacuum.• Too long time for post pressure.• Too long time for vacuum break.• Vacuum pump trips.• Door pre condition fails.• Process end.• Chamber Temperature sensor 1 probe fail.• Chamber Temperature sensor 2 probe fail.• Chamber Temperature sensor 3 probe fail.• Chamber Temperature sensor 4 probe fail.• Chamber Temperature sensor 5 probe fail.• Chamber Pressure Sensor (Transmitter) Fail.	

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

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

Inference:

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



INSALLATION 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



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11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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INSALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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INSALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

16.0 ABBREVIATIONS:

%	:	Percent
&	:	And
°C	:	Degree Centigrade
AC	:	Alternate Current
BSP	:	British Standard for Pipe Threading
cGMP	:	Current Good Manufacturing Practice
Cm ²	:	centimeter square
D	:	Depth
db	:	Decibel
DC	:	Direct current
FS	:	Full Scale
GA	:	General Arrangement
H	:	Height
HPHV	:	High Pressure High Vacuum
HMI	:	Human Machine Interface
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
I/P	:	Input
IB	:	Injection block
ID	:	Inner Diameter
IQ	:	Installation Qualification
Kg	:	Kilogram
Ltd.	:	limited
MCB	:	Miniature Circuit Breaker
Min	:	Minute
mm	:	Millimeter
MOC	:	Material of Construction
NA	:	Not Applicable
NB	:	Nominal Bore
No.	:	Number



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

O/P	:	Output
OD	:	Outer Diameter
P & ID	:	Piping and Instrumentation Diagram
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
RH	:	Relative Humidity
RPM	:	Revolution per Minute
RTD	:	Resistance Temperature Detector
SMPS	:	Switch Mode Power Supply
SS	:	Stainless Steel
TC	:	Triclover
Temp.	:	Temperature
URS	:	User Requirement Specification
V	:	Volt
W	:	Width



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INSALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			