DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

HIGH PRESSURE HIGH VACUUM

STEAM STERILIZER

SIZE: 750 x 750 x 1200 mm

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

PROTOCOL CONTENTS

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

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)			

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **HPHV steam sterilizer (Make: Machinfabrik Industries Pvt. Ltd.)** for ……..
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

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	• 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	• 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.
Engineering	• 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. ➢ 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.

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical products in accordance with cGMP principles

6.0 BRIEF EQUIPMENT DESCRIPTION:

The High Pressure High Vacuum Sterilizer has been a unique Sterilization System offered by M/s. …….. as it can be efficiently used to perform two types of sterilization processes:

- Standard Program
- H.P.H.V.

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

- Chamber Leak Test
- Warm Up Cycle
- Bowie Dick test

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

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.

STANDARD STEAM STERILIZER:

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
- Heat up
- Sterilization Hold
- Vacuum drying
- 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.

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared …….. The manufacturer of equipment ensures complies with User Requirement Specification.

Equipment HPHV Steam Sterilizer	HPHV Steam Sterilizer
Chamber Size	750 (W) X 750 (H) X 1200 (D) mm
Chamber Volume	675 Liters
Working Pressure	Up to 2.2 Kg/Cm^2 (G)
Working Temperature	Up to 134^0C

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: Double Door Autoclave is designed for the sterilization of clean room garments, articles and supporting machine parts & accessories which has to be used in production in three piece line.	All the loaded articles and supporting accessories should be sterile after performing the validated cycles.	Process Requirement
Working: In this process, Steam introduces in the chamber and it acts or works on the placed articles or container which is being kept in the chamber for sterilization.	During Steam Sterilization, Steam distribution should be uniform in the chamber.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

8.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria			
Utility connections should be available as per the manufacturer's specification.				
	Pure Steam for Chamber	**Plant Steam for Jacket**	**Compressed Air**	**Water for Vacuum System**
Pressure	1.2 – 1.4 kg/cm2 (g	1.5 kg/cm2 (g)	6 – 7 kg/cm^2	1.2 kg/cm2 (g)
Quality	Dry & Saturated	Dry & Saturated	Lubricated and moister free	WFI
Cycle Demand	36 kg/cycle	9 kg/cycle	-	-
Line Size	¾" OD	½' NB	½' NB	½' NB
End Connection	Triclover	Triclover	Triclover	Triclover
Peak demand	1.20 kg/min	0.84 kg/min	0.2 m3/hr	7 pm for 35 min cycle
Electricity	**Power:** 415 V – 3 PH – 50 Hz AC, 4 Wire Supply. **Control:** 230 V – 1 PH – 50 Hz Stabilized AC Supply.			
Connected Load	Resistive Load **:** NA			
	Inductive Connected Load : 3 HP			
Incoming electric cable size	4 Core x 2.5 Sq.mm Copper cable or			
	4 Core x 2.5 Sq.mm Aluminum cable			

WORKING CONDITION AND TEST PARAMETER

Parameters	Chamber	Jacket	Condenser		Air Pocket
			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°C	134°C	NA	134°C	60°C
Vacuum	Full	NA	NA	Full	Partial
Pneumatic Test Pressure	NA	NA	NA	NA	4.5 kg/cm^2 (g)

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
1.0 Shell design		
Chamber		
Internal Size	750 (W) X 750 (H) X 1200 (D) mm	Design Requirement
Plate Thickness	6 mm	Design Requirement
Chamber Volume	675 Liters	Design Requirement
Material of construction	SS316L	Design Requirement
Finish	Ra ≤ 0.8 µm	Design Requirement
Design Code	ASME SEC VIII DIV – 1	Design Requirement
Welding Joint Radiography	10% of Weld Length	Design Requirement
Jacket		
Type	Full	Design Requirement
Plate Thickness	5 mm	Design Requirement
Material of construction	SS304	Design Requirement
Air Pocket		
Plate Thickness	5 mm	Design Requirement
Material of construction	SS304	Design Requirement
Shell Insulation		
Insulation Material	Resin Bonded Glass wool	Design Requirement
Insulation Thickness	50 mm	Design Requirement
Insulation Skin Temperature	55° C (Subjected to room temperature 23 ± 2^0C)	Design Requirement
Insulation Cover Thickness	0.558 (24G)	Design Requirement
Insulation Cover material	SS304	Design Requirement
Stand		
Stand material	SS304	Design Requirement
Skid		
Skid material	SS304	Design Requirement
Rails & Baffles		
Rail Pipe Material	SS316L	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Steam Baffle Material	SS316L	Design Requirement
Validation Port with Dummy Adaptor		
MOC	SS316	Design Requirement
No of probes arrangement in each port	8 Nos.	Design Requirement
Qty of port	2 Nos.	Design Requirement
Port for Chamber Flexible RTD Sensor		
MOC	SS 316	Design Requirement
No of Sensor	8 Nos.arrangement in each port	Design Requirement
Quantity	1 No.	Design Requirement
Compound Gauge		
Jacket		
Make	Forbes Marshall	Design Requirement
Type	Bourdon	Design Requirement
Mounting	Panel	Design Requirement
Range	1 To 6 kg/cm^2 (g)	Design Requirement
MOC	SS316 for Contact Part SS304 for Non Contact Part	Design Requirement
Accuracy	± 1% FS	Design Requirement
Connection	3/8" BSP, Back Connection	Design Requirement
Location	Loading Side	Design Requirement
Function	Indication of Jacket Pressure	Design Requirement
Chamber		
Make	Forbes Marshall	Design Requirement
Type	Bourdon	Design Requirement
Mounting	Panel	Design Requirement
Range	1 To 6 kg/cm^2 (g)	Design Requirement
MOC	SS316 for Contact Part SS304 for Non Contact Part	Design Requirement
Accuracy	± 1% FS	Design Requirement
Connection	3/8" BSP, Back Connection	Design Requirement
Location	Unloading and Loading Side	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Function	Indication Of Chamber pressure	Design Requirement
DOOR & DOOR COMPONENTS		
Door		
Type	Vertical Sliding	Design Requirement
Quantity	2 Nos.	Design Requirement
Finish	Ra ≤ 0.8 µm	Design Requirement
Material	SS316L (Only for Contact Part)	Design Requirement
Door Insulation System		
Insulation Material	Resin Bonded Glass wool	Design Requirement
Insulation Thickness	50 mm	Design Requirement
Insulation Outer Cover material	SS304	Design Requirement
Insulation Outer Cover material thickness	1.21 mm (18G)	Design Requirement
Door Components		
Door Components material	SS304	Design Requirement
Door Extension material	SS304	Design Requirement
Door Gasket		
Material	Food Grade Silicon	Design Requirement
Size	20 (OD) X 9 (ID) X 3535 (L) mm	Design Requirement
Specification	In accordance with USFDA 21CFR Section 177.2600	Design Requirement
Working Temperature	134 ^{0}C	Design Requirement
Working Pressure	3 kg/cm^2 (g)	Design Requirement
Quantity	2 Nos.	Design Requirement
Function	To seal gap between chamber & door	Design Requirement
Door Operating Cylinder		
Make	Aircon Pneumatic	Design Requirement
Mounting	Vertical	Design Requirement
Type	Telescopic	Design Requirement
Size	860 Stroke	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Quantity	2 Nos.	Design Requirement
Function	Door Operation.	Design Requirement
Solenoid Valves for Door Operating Cylinder		
Make	Festo/ Janatics	Design Requirement
Type	JMFH - 5¼, Double coil	Design Requirement
Operating Pressure Range:	1.5 To 8.0 bar	Design Requirement
Coil Supply	1 PH – 230V – 50Hz	Design Requirement
Quantity	2 Nos.	Design Requirement
Function	To operate the door operating cylinder	Design Requirement
Door Locking Cylinder		
Make	JANATICS/Rotex	Design Requirement
Mounting	Horizontal	Design Requirement
Type	Double Acting	Design Requirement
Size	40 Bore X 25 Stroke	Design Requirement
Quantity	2 Nos.	Design Requirement
Function	To prevent accidental fall of door when it is in closed position.	Design Requirement
Solenoid Valves for Door Locking Cylinder		
Make	FESTO/Janatics	Design Requirement
Type	JMFH - 5 ¼, Double Coil	Design Requirement
Operating Pressure Range	1.5 to 8.0 bar	Design Requirement
Coil Supply	1 Phase, 230 V, 50 Hz	Design Requirement
Quantity	2 Nos.	Design Requirement
Function	To operate the door locking cylinder	Design Requirement
Solenoid Valves for Gasket Pressurization/Retraction		
Make	Patcon	Design Requirement
Model	2 Way On/Off	Design Requirement
Coil Supply	1 Phase, 230 V, 50 Hz	Design Requirement
Quantity	5 Nos.	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Function	To pressurize and retract the gasket to facilitate the door opening and closing.	Design Requirement
Regulator		
Make	Janatics/ Rotex	Design Requirement
Model	R 13614	Design Requirement
Size	¼" BSP	Design Requirement
Range	0.5 to 10 Bar	Design Requirement
Function	One is used for door operation & the other one is used for gasket pressurization	Design Requirement
Filter Regulator Lubricator		
Make	Janatics/ Rotex	Design Requirement
Model	FRC136134	Design Requirement
Size	¼" BSP	Design Requirement
Range	0.5 to 10 Bar	Design Requirement
Function	To filter, regulate & lubricate the incoming compressed air.	Design Requirement
Pressure Switch		
Make	ORION	Design Requirement
Model	MG H04 KS 10	Design Requirement
Range	0.2 to 3.6 bar	Design Requirement
Quantity	2 Nos.	Design Requirement
Function	To set the pressure level for the gasket on unloading and Loading side	Design Requirement
Vacuum Switch		
Make	ORION	Design Requirement
Model	MG V00 KA 10	Design Requirement
Range	760 mm to 100 mm of Hg (Vacuum)	Design Requirement
Quantity	2 Nos.	Design Requirement
Function	To set the pressure level for the gasket on unloading and Loading side.	Design Requirement
Ejector		
Make	FESTO	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Model	Vad ¼	Design Requirement
Size	¼" BSP	Design Requirement
Function	To retract door gasket before opening door.	Design Requirement
Compound Gauges		
Make	FORBES MARSHALL	Design Requirement
Type	Bourdon	Design Requirement
Mounting	Panel	Design Requirement
MOC	SS 316 L for Contact Part SS 304 for Non Contact Part	Design Requirement
Range	-1 To 6 kg/cm^2 (g)	Design Requirement
Quantity	3 Nos.	Design Requirement
Accuracy	± 1% FS	Design Requirement
Connection	3/8" BSP (M)	Design Requirement
Compound Gauge at Loading	Loading side gasket pressure & Unloading side	Design Requirement
Compound Gauge at unloading side	Unloading side gasket pressure	Design Requirement
Function	Indication of Loading & Unloading gasket pressure.	Design Requirement
Limit Switch		
Make	BOHMEN	Design Requirement
Model	1 NO + 1 NC	Design Requirement
Type	Roller Lever	Design Requirement
Quantity	4 Nos.	Design Requirement
Function	Sensing the door position	Design Requirement
Photocell Sensor		
Make	P & F/Optex	Design Requirement
Model	M5/MV5/32/115	Design Requirement
Type	Single Path	Design Requirement
Quantity	2 Sets	Design Requirement
Function	Door obstruction safety.	Design Requirement
2.0 Panelling		

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Location of Paneling	On all four sides (As per layout)	Design Requirement
Paneling Finish	Ra ≤ 1.0	Design Requirement
Mounting	On Skid	Design Requirement
Material of panelling	SS304	Design Requirement
Contamination Seal Material	SS304 at Unloading Side	Design Requirement
3.0 PROCESS CONTROL SYSTEM		
Piping		
Piping Material	SS 316 L for Contact Part	Design Requirement
End Connection	Triclover	Design Requirement
Piping Material	SS 316 L for Non Contact Part	Design Requirement
End Connection	Threaded	Design Requirement
Welding	Argon Welding	Design Requirement
Pneumatic Piston Type Valve with Solenoid		
Make	Machinfabrik	Design Requirement
MOC	SS 316 L	Design Requirement
Type	Single Acting	Design Requirement
End Connection	Threaded/ Triclover	Design Requirement
	Function / **Size** / **Valve no.** Jacket Steam In / ½" BSP / 101 Chamber Exhaust / ½" OD TC / 201 Chamber Condensate / ½" OD TC / 209 Chamber Steam In / ½" OD TC / 210 Chamber Steam (small) / ½" OD TC / 210 A	Design Requirement
Manual Ball Valve		
Make	President	Design Requirement
Type	3PC Design	Design Requirement
End Connection	Triclover	Design Requirement
Valve no.	2210 A	Design Requirement
Size	½" OD TC (SS 316 L)	Design Requirement
Function	Chamber Steam In	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Manual Needle Valve		
Make	President SS304	Design Requirement
Type	3PC Design	Design Requirement
End Connection	Threaded	Design Requirement
Valve no.	2201	Design Requirement
Size	½" BSP	Design Requirement
Function	Chamber Exhaust	Design Requirement
Non Return Valve		
Make	LEADER	Design Requirement
MOC	BRASS	Design Requirement
End Connection	Threaded	Design Requirement
Valve no.	29	Design Requirement
Size	½" BSP	Design Requirement
Function	to prevent backflow from the drain line to chamber	Design Requirement
Safety Valve		
Make	Teleflo/Fainger Leser	Design Requirement
MOC	SS 304	Design Requirement
Type	Spring Loaded	Design Requirement
Range	0 to 3 kg/cm^2 (g)	Design Requirement
End Connection	Threaded	Design Requirement
	Function / **Size** / **Valve no.** To protect the jacket from over pressure conditions / 3/4" BSP / 10 To protect the chamber from over pressure conditions / 3/4" BSP / 20	Design Requirement
Steam Trap		
Make	Forbes Marshall	Design Requirement
Model	SOFT31-0	Design Requirement
Type	Float Type	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
MOC	Cast Iron with Brass Contact Parts	Design Requirement
End Connection	Threaded	Design Requirement
Valve no.	12	Design Requirement
Size	½" BSP	Design Requirement
Function	Jacket Condensate	Design Requirement
Valve no.	24	Design Requirement
Size	½" BSP	Design Requirement
Function	Chamber Condensate	Design Requirement
Pressure Switch		
Make	Orion	Design Requirement
Pressure housing MOC	SS316	Design Requirement
Range	0.2 to 3.6 bar	Design Requirement
End Connection	Threaded	Design Requirement
Qty.	01 Nos.	Design Requirement
Valve no.	17	Design Requirement
Model	MG H04 KS 10	Design Requirement
Function	To set pressure level of Jacket	Design Requirement
Pressure Switch		
Make	ORION	Design Requirement
Model	MG LP KS 10	Design Requirement
Pressure housing MOC	SS 316	Design Requirement
Range	0.067 to 0.213 bar	Design Requirement
End Connection	Threaded	Design Requirement
Valve No	20M	Design Requirement
Quantity	1 No.	Design Requirement
Function	To set pressure level of chamber	Design Requirement
4.0 Vacuum System		
Vacuum pump & motor		
Make	New Genre/ PPI	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Type	Watering Type	Design Requirement
Capacity	50 m3/hr	Design Requirement
Location	On Skid	Design Requirement
HP / RPM	HP/ 2850 RPM	Design Requirement
Function :	To create vacuum in the chamber	Design Requirement
Steam Condenser		
Type	Shell & Tube	Design Requirement
Transfer area	0.24 m2	Design Requirement
Location	On Skid	Design Requirement
Material	Material : SS304	Design Requirement
Function	To condense the exhaust steam (from Chamber) before entering the vacuum pump.	Design Requirement
Pneumatic Piston Type valve		
Make	MACHINFABR IK	Design Requirement
MOC	SS 316 L	Design Requirement
Type	Single Acting	Design Requirement
End Connection	Triclover/ Threaded	Design Requirement
	Function **Size** **Valve no.** Chamber Vacuum 1” OD TC 202 Chamber Filter Air in ½” OD TC 208 Vacuum pump softened ½” BSP 301 water in	Design Requirement
Non Return Valve		
Make	LEADER	Design Requirement
MOC	Brass	Design Requirement
End Connection	Threaded	Design Requirement
Valve no.	2D	Design Requirement
Size	1” BSP	Design Requirement
Function	To prevent backflow from vacuum pump to chamber	Design Requirement
Air Filter		

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Make	SARTORIUS/PALL	Design Requirement
Filter Retention	0.2 micron	Design Requirement
End Connection	1 ½" OD TC	Design Requirement
Location	On Unloading Side.	Design Requirement
Function	To filter the air before entering into the Chamber	Design Requirement
5.0 ELECTRICAL CONTROL PANEL & POWER PANEL		
Type	Inbuilt	Design Requirement
Material	SS304	Design Requirement
Switch Gear		
Contractor	SIEMENS	Design Requirement
Miniature Circuit Breaker	SIEMENS	Design Requirement
Over Load Relay	SIEMENS	Design Requirement
Indication Lamp	Techink/Mimic	Design Requirement
Terminal Block	Elmex /Connect well	Design Requirement
CONTROL INDICATION ON UNLOADING SIDE		
Push Buttons with indication lamps	Color coded push buttons with indication lamps are provided for the following: • Unloading door open. • Unloading door close. • Unloading door acknowledge. • Emergency stop.	Design Requirement
Indication lamps	Color coded indication lamps are provided for the following: • Door precondition indication. • Process on/end indication.	Design Requirement
CONTROL INDICATION ON LOADING SIDE		

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Push Buttons with indication lamps	Color coded push buttons with indication lamps are provided for the following: • Loading door open. • Loading door close. • Emergency stop. • Control on/off switch. Heater on/off switch.	Design Requirement
Indication lamps	Color coded indication lamps are provided for the following: • Door precondition indication. • Alarm Indication.	Design Requirement
MMI	The operator interface (E 1061) is fitted onto the Control Panel on the loading side.	Design Requirement
Printer	The Printer is fitted onto the Control Panel on the loading side.	Design Requirement
Strip Chart Recorder	The Strip Chart Recorder is fitted onto the Control Panel on the loading side.	Design Requirement
6.0 INSTRUMENTATION		
PLC		
Make	MITSUBISHI	Design Requirement
Model	FX1N 24MRES	Design Requirement
No. of digital inputs	14 Nos.	Design Requirement
No. of digital inputs used:	5 Nos.	Design Requirement
Type of input	24V DC	Design Requirement
No. of digital outputs	10 Nos.	Design Requirement
No. of digital outputs used	10 Nos.	Design Requirement
Type of output	Potential Free Relay	Design Requirement
Function	To control the process automatically.	Design Requirement
Extension Card (O/P Card)		
Make	MITSUBISHI	Design Requirement
Model	FX2N 8EYRES	Design Requirement
No. of digital Outputs	08Nos.	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
No. of digital Outputs s used	01Nos.	Design Requirement
Type of output	230 V AC	Design Requirement
Function	To add additional output to PLC.	Design Requirement
Analog I/P Card		
Make	MITSUBISHI	Design Requirement
Model	FX1N 2ADBD	Design Requirement
No. of analog inputs	02Nos.	Design Requirement
No. of analog inputs used	02Nos.	Design Requirement
Type of analog input	4 to 20 mA	Design Requirement
Quantity	1 No.	Design Requirement
Function	To give analog input to PLC.	Design Requirement
Analog I/P Card		
Make	MITSUBISHI	Design Requirement
Model	FX1N 4ADPT	Design Requirement
No. of analog inputs	04Nos.	Design Requirement
No. of analog inputs used	04Nos.	Design Requirement
Type of analog input	Pt 100	Design Requirement
Quantity	1 No.	Design Requirement
Function	To give analog input to PLC	Design Requirement
MMI		
Make	MITSUBISHI (BEIJER Electronics)	Design Requirement
Model	E 1061	Design Requirement
Printer Port	Rs 232	Design Requirement
Function	To start the process & display online parameters.	Design Requirement
Printer		
Make	EPSON	Design Requirement
Model	LX 310	Design Requirement
Function	To print online parameters	Design Requirement
D.C. Source		

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Make	SHAVISON	Design Requirement
Model	G31- 60 - 24	Design Requirement
Type	SMPS	Design Requirement
I/P Voltage	230 V AC	Design Requirement
O/P Voltage	24 V DC, 2.5 A	Design Requirement
Function	To provide 24 V DC, 2.5 A supply to PLC.	Design Requirement
Pressure Transmitter		
Make	JUMO	Design Requirement
Range	0 to 4 bar (A) [-1 to 3 bar (g)]	Design Requirement
Accuracy	0.25%	Design Requirement
O/P	4 to 20 mA	Design Requirement
End Connection	½” BSP	Design Requirement
Quantity	1 No.	Design Requirement
Function	To convert pressure input to 4 - 20 mA.	Design Requirement
Temperature Transmitter		
Make	RADIX	Design Requirement
Range	0 to 200^{0}C	Design Requirement
Accuracy	± 0.1% of FS	Design Requirement
I/P	PT 100	Design Requirement
O/P	4 to 20 mA	Design Requirement
Quantity	1 No	Design Requirement
Function	To convert temperature input to 4 - 20 mA	Design Requirement
Temperature Sensor (Inside the chamber)		
Make	RADIX	Design Requirement
Type	PT100/ Duplex/ 3 Wire/ Flexible	Design Requirement
Size	6 mm Tip Dia. X 2” Long	Design Requirement
Cable Length	5 Meter Long	Design Requirement
Accuracy	Class A	Design Requirement
Quantity	4 Nos.	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Temperature Sensor (Chamber Condensate)		
Make	RADIX	Design Requirement
Type	PT100/ Duplex/ 3 Wire/ Fixed	Design Requirement
Size	6 mm Tip Dia. X 4" Long	Design Requirement
Accuracy	Class A	Design Requirement
Quantity	2 Nos.	Design Requirement
Temperature Indicator cum Controller		
Make	RADIX	Design Requirement
Model	Prima 481	Design Requirement
No. of Set Point	Single	Design Requirement
Range	0 to 200^0C	Design Requirement
Quantity	1 No	Design Requirement
Function	For manual operation in case of PLC failure.	Design Requirement
Strip Chart Recorder		
Make	YOKOGAWA	Design Requirement
No. of Channels	Six	Design Requirement
No. & Type of Inputs	5T + 1P	Design Requirement
Temperature Sensors	5 Nos., PT100, 3 Wire	Design Requirement
Range	0 to 200^0C	Design Requirement
Pressure	1 No., 4 to 20 mA	Design Requirement
Range	1 to 3 bar	Design Requirement
7.0 Handling Accessories		
Carriage		
Type	Full	Design Requirement
Material	SS316L	Design Requirement
Qty	1 No	Design Requirement
Arrangement	Shelves	Design Requirement
Pattern	Perforated	Design Requirement
Layer	2 Nos. equispaced	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Qty	4 Nos.	Design Requirement
Trolley		
Type	Full	Design Requirement
Material	SS304	Design Requirement
Qty	2 Nos.	Design Requirement

Checked By
(Engineering)
Sign/Date: _____

Verified By
(Quality Assurance)
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

8.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts name	Material of Construction
1.	Chamber	SS 316 L
2.	Jacket	SS 304
3.	Air Pocket	SS 304
4.	Insulation Cover Material	SS 304
5.	Stand	SS 304
6.	Skid	SS 304
7.	Rail Pipe	SS 316 L
8.	Steam & Vacuum Baffle	SS 316 L
9.	Validation Port with Dummy Adaptor	SS 316
10.	Door	SS 316 L
11.	Door Insulation System	SS 304
12.	Door Components	SS 304
13.	Pneumatic Piston Type Valve with Solenoid	SS 316 L
14.	Manual Diaphragm Valve	SS 316 L
15.	Chamber Exhaust	SS 304
16.	Chamber Steam In	SS 316 L
17.	Recirculation Sampling	SS 316 L
18.	Side Pocket Sampling	SS 316 L
19.	Chamber Drain	SS 316 L
20.	Manual Needle Valve	SS 304

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

S.No.	Parts name	Material of Construction
21.	Non Return Valve (TC End)	SS 316 L
22.	Non Return Valve (Threaded)	Brass
23.	Safety Valve	SS 304
24.	Steam Trap	Cast Iron with Brass Contact Parts
25.	Float Switch	SS 316
26.	Pressure Switch	SS 304
27.	Water Filter	SS 316 L
28.	Gear Box	SS 316 L
29.	Steam Condenser	SS304
30.	Pneumatic Piston Type Valve	SS 316 L

Checked By
(Engineering)
Sign/Date: _____

Verified By
(Quality Assurance)
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

8.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Earthing	Proper Earthing should be provided.	Safety Requirement
Doors Inter Locks	• 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.	Safety Requirement
Door Obstruction Safety	While the door is closing, the door will retract to open if obstructed by hand or by any other object	Safety Requirement
Door/Gasket Operation	Electro -Pneumatic	Safety Requirement
Door Locking System	Pneumatic through process	Safety Requirement
Alarms	• If the chamber temperature overshoots. • If chamber temperature falls below specified level & the timer stops counting • If chamber Vacuum leak test is failed.	

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
	• If chamber temperature falls further below specified level & the timer resets previously counted time. • If chamber pressure is greater than the set value. • Too long time for heat up. • Too long time for pre pressure. • Too long time for pre vacuum. • Too long time for post pressure. • Too long time for post vacuum. • Too long time for Vacuum break. • If 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	Safety Requirement
PROCESS DETAILS		
AUTO MODE	Vacuum Leak Test – 1	
	Vacuum Leak Test (HOT) - 2	
	Warm Up Cycle – 3	
	Bowie and Dick Test – 4	
	Standard Process (Gravity Displacement Program) – 5 & 6 HPHV Process (Pre Vacuum Program with Vacuum Drying) – 7,8,9,10	
Programmed Parameters	Set through Man Machine Interface	

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

Critical Variables	Acceptance Criteria	Reference
Parameter Change	Password Protected (3 Level Password Protection for E 1061)	
Manual Mode	Processes can be performed manually with rocker switch, temperature indicator cum controller and Compound gauges	

Checked By
(Engineering)
Sign/Date: _____

Verified By
(Quality Assurance)
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

8.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Double Door Autoclave.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

Reference: (1) Specifications and Requirements as specified in PO and URS.

(2) Operating and service manual for Double Door Autoclave.

9.0 DOCUMENTS TO BE ATTACHED:

- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AC	:	Alternate Current
BSP	:	British Standard Pipe
CI	:	Cast Iron
CFR	:	Code of Federal Regulation
cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate
db	:	Decibel
DDA	:	Double Door Autoclave
DQ	:	Design 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
MMI	:	Man 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

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

RPM	:	Revolution per Minute
RTD	:	Resistance Temperature Detector
SMPS	:	Switched Mode Power Supply
SS	:	Stainless Steel
URS	:	User Requirement Specification
USFDA	:	United State Food and Drug Administration
V	:	Volt
W	:	Width
D	:	Depth
H	:	Height
Press.	:	Pressure
Temp.	:	Temperature
TC	:	Triclover
DC	:	Direct current
AC	:	Alternate current
PLC	:	Programmable Logic Controller
0C	:	Degree Centigrade
PDQ	:	Protocol design qualification
IB	:	Injection block
&	:	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

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STTEAM STERILIZER

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			