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

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

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

PROTOCOL CONTENTS

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

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)			

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM 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 & ID's provided by Vendor shall be verified during Design Qualification.

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

4.0 RESPONSQBILITY:

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	RESPONSQBILITIES
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 STEAM 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 Sterilizer manufactured by **M/s. Machin fabrik 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. Machin fabrik 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.

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.

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 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 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
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 134^0c

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM 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

8.2 DESIGN SPECIFICATION:

WORKING CONDITIONS & TEST PRESSURES

	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	134^0C	134^0C	NA	134^0C	60^0C
Vacuum	Full	NA	NA	Full	Partial
Pneumatic Test pressure	NA	NA	NA	NA	4.5 kg/cm^2 (g)

8.2.2 SHELL DESIGN

8.2.2.1 CONSTRUCTIONAL DETAILS

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
CHAMBER		
Internal Size	600 (W) X 600 (H) X 900 (D) mm	Design Requirements
Plate Thickness	6 mm	Design Requirements
Material	SS316L	Design Requirements
Finish	Ra ≤ 0.8 µm	Design Requirements
Design Code	ASME SEC VIII DIV – 1	Design Requirements
Welding Joint Radiography	10% of Weld Length	Design Requirements
JACKET		
Type	Full	Design Requirements
Plate Thickness	5 mm	Design Requirements
Material	SS304	Design Requirements
AIR POCKET		
Plate Thickness	5 mm	Design Requirements
Material	SS304	Design Requirements

8.2.2.2 SHELL INSULATION

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Insulation Material	Resin Bonded Glasswool	Design Requirements
Insulation Thickness	50 mm	Design Requirements
Insulation Skin Temperature (Average)	55^0C (Subjected to room temperature 23 ± 2^0C)	Design Requirements
Insulation Cover Material	SS304	Design Requirements
Insulation Cover Thickness	0.558 mm (24G)	Design Requirements

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

8.2.2.3 RAILS & BAFFLES

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Gauges		
Compound Gauge (1L) **Refer P & I Diagram:** **22-3-1453**	Make : Forbes Marshall Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm^2 (g) MOC : SS316L for Contact Part SS304 for Non Contact Part Accuracy: ± 1% FS Connection : 3/8" BSP (M) Location : Loading Side Qty : 1 No Function : Indication of jacket pressure.	Design Requirements
Compound Gauges **(2C, 2C1)** **Refer P & I Diagram:** **22-3-1453**	Make : Forbes Marshall Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm^2 (g) MOC : SS316L for Contact Part SS304 for Non Contact Part Accuracy : ± 1% FS Connection : 3/8" BSP (M) Location : Unloading and Loading Side Qty : 2 Nos Function : Indication of chamber pressure.	Design Requirements
Validation Port with **Dummy Adaptor**	MOC : SS316 No of sensor arrangement in each port : 8 Nos Qty : 2 Nos	Design Requirements
Port for Chamber Flexible **RTD Sensor**	MOC : SS316 No of sensor arrangement in port : 8 Nos Qty : 1 No	Design Requirements

8.2.2.4 DOOR & DOOR COMPONENTS

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
DOOR		
Type	Vertical Sliding	Design Requirements
Quantity	Two	Design Requirements
Material	SS316L (Only for Contact Part)	Design Requirements
Finish	Ra ≤ 0.8 µm	Design Requirements
Insulation System		
Insulation Material	Resin Bonded Glasswool	Design Requirements
Insulation Thickness	50 mm	Design Requirements
Insulation Outer Cover Material	SS304	Design Requirements
Insulation Outer Cover Material Thickness	1.21 mm (18G)	Design Requirements
DOOR COMPONENTS		
Door Compoent Material	SS304	Design Requirements
Door Extension Material	SS304	Design Requirements
Door Gasket	Material : Food Grade Silicon Size : 20 (OD) X 9 (ID) X 2335 (L) mm Specification : In accordance with USFDA 21CFR Section 177.2600 Working Temperature : 134^0C Working Pressure : 3 kg/cm^2 (g) Qty : 2 Nos Function : To seal gap between chamber & door.	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Door Operating Cylinder (5A, 5B) Refer Pneumatic Diagram: 25-3-1227	Make : Janatics Type : Telescopic Mounting : Vertical Type : Double Acting Size : 63 bore x 710 Stroke Qty : 2 Nos Function : Door Operation.	Design Requirements
Solenoid Valves for Door Operating Cylinder (501, 502 & 503, 504) Refer Pneumatic Diagram: 25-3-1227	Make : Festo Type : JMFH - 5 ¼, Double Coil Operating Pressure Range : 1.5 To 8.0 bar Coil Supply : 1PH – 230V – 50Hz Qty : 2 Nos Function : To operate the door operating cylinder	Design Requirements
Door Locking Cylinder (5C, 5D) Refer Pneumatic Diagram : 25-3-1227	Make : Janatics Mounting : Horizontal Type : Double Acting Size : 40 Bore X 25 Stroke Qty : 2 Nos Function : To prevent accidental fall of door when it is in closed position.	Design Requirements
Solenoid Valves for Door Locking Cylinder (509, 515 & 510, 514) Refer Pneumatic Diagram : 25-3-1219	Make : Festo Type : JMFH - 5 ¼, Double Coil Operating Pressure Range : 1.5 To 8.0 bar Coil Supply : 1PH – 230V – 50Hz Qty : 2 Nos Function : To operate the door locking cylinder.	Design Requirements
Solenoid Valves for Gasket	Make : Patcon	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Pressurization/Retraction (505, 506, 507, 508, 511) Refer Pneumatic Diagram: 25-3-1227	Model : 2 Way On/Off Coil Supply : 1PH – 230V – 50Hz Qty : 5 Nos Function : To pressurize and retract the gasket to facilitate the door opening and closing.	
Regulator (5J, 5K) Refer Pneumatic Diagram: 25-3-1227	Make : Janatics Model : R 13614 Size : ¼" BSP Range : 0.5 To 10 Bar Qty : 2 Nos Function : One is used for door operation & the other one is used for gasket pressurization.	Design Requirements
Filter Regulator Lubricator (5I) Refer Pneumatic Diagram: 25-3-1227	Make : Janatics Model : FRC136134 Size : ¼" BSP Range : 0.5 To 10 Bar Qty : 1 No Function : To filter, regulate & lubricate the incoming compressed air.	Design Requirements
Pressure Switch (56, 57) Refer Pneumatic Diagram: 25-3-1227	Make : Orion Model : MG H04 KS 10 Range : 0.2 – 3.6 bar Qty: 2 Nos Function : To set the pressure level for the gasket on Unloading and Loading Side.	Design Requirements
Vacuum Switch (58, 59)	Make : Orion Model : MG V00 KA 10	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Refer Pneumatic Diagram: 25-3-1219	Range : 760 mm to 100 mm of Hg (Vacuum) Qty: 2 Nos Function : To set the vacuum level for the gasket on the Unloading and Loading Side.	
Compound Gauges (53A, 53B, 54) Refer Pneumatic Diagram: 25-3-1227	Make : Forbes Marshall Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm^2 (g) MOC : SS316L for Contact Part SS304 for Non Contact Part Accuracy : ± 1% FS Qty : 3 Nos Connection : 3/8" BSP (M) **Locations :** 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.	Design Requirements
Ejector (55) Refer Pneumatic Diagram: 25-3-1227	Make : Festo Model : Vad ¼ Size : ¼" BSP Function : To retract door gasket before opening door.	Design Requirements
Limit Switch (5E, 5F, 5G, 5H) Refer Pneumatic Diagram:	Make : Bohmen Model : 1 NO + 1 NC Type : MLRLS	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
25-3-1227	Qty : 4 Nos Function : Sensing the door position.	
Photocell Sensor	Make : P & F Type : Single Path Model : M100/MV100-RT/76a/103/115 / Z2T-2000(P) Qty : 2 Sets Function : Door obstruction safety.	Design Requirements

8.2.2.5 PANELLING

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Location of Panelling	On all four sides (As per layout)	Design Requirements
Material of Panelling	SS304	Design Requirements
Panelling Finish	Ra ≤ 1.0 µm	Design Requirements
. Mounting	On Skid	Design Requirements
Contamination Seal	Material : SS304 Location : Unloading Side	Design Requirements

8.2.3 PROCESS CONTROL SYSTEM

<table>
<tr><th>CRITICAL VARIABLE</th><th>ACCEPTANCE CRITERIA</th><th>REFFERENCE</th></tr>
<tr><td>Piping</td><td>Piping Material : SS316L for Contact Part
End Connection : Triclover
Piping Material : SS316L for Non Contact Part
End Connection : Threaded
Welding : Argon Welding</td><td>Process Requirements</td></tr>
<tr><td>Pneumatic Piston Type Valve
with Solenoid
(101, 201, 209, 210, 210A)
Refer P & I diagram:</td><td>Make : Machinfabrik
MOC : SS316L
Type : Single Acting
End Connection : Threaded/ Plain End
Qty :3 Nos
<table>
<tr><td>Part No</td><td>Size</td><td>Function</td></tr>
</table></td><td>Process Requirements</td></tr>
</table>

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

<table>
<tr><th>CRITICAL VARIABLE</th><th colspan="4">ACCEPTANCE CRITERIA</th><th>REFFERENCE</th></tr>
<tr><td rowspan="3">22-3-1453</td><td colspan="4">101 | ½” BSP | Jacket Steam in</td><td></td></tr>
<tr><td colspan="4">201 | ¾” OD | Chamber Exhaust</td><td></td></tr>
<tr><td colspan="4">209 | ¾” OD | Chamber</td><td></td></tr>
<tr><td rowspan="4">Proportionate Pneumatic
Piston Type Valve</td><td colspan="4">Make : Gemu
MOC : SS316 L
Type : Single Acting
End Connection : Threaded / Plain end
Qty : 3 Nos</td><td rowspan="4">Process Requirements</td></tr>
<tr><td>Part No.</td><td colspan="2">Size</td><td>Function</td></tr>
<tr><td>210</td><td colspan="2">¾” OD</td><td>Chamber Steam In</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td rowspan="4">Manual Needle Valve
(2201)
Refer P & I diagram:
22-3-1453</td><td colspan="4">Make : President
MOC : SS304
End Connection : Threaded
Qty : 1 No</td><td rowspan="4">Process Requirements</td></tr>
<tr><td>Part No</td><td colspan="2">Process Requirements</td><td>Function</td></tr>
<tr><td>2201</td><td colspan="2">Process Requirements</td><td>Chamber Exhaust</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td rowspan="5">Safety Valve
(10, 20)
Refer P & I diagram:
22-3-1453</td><td colspan="4">Make : Fainger Leser
Type : Spring Loaded
MOC : SS316
Range : 0 to 3 kg/cm^2 (g)
End Connection : Threaded
Qty : 2 Nos</td><td rowspan="5">Process Requirements</td></tr>
<tr><td>Part No</td><td>Size</td><td colspan="2">Function</td></tr>
<tr><td>10</td><td>¾” BSP</td><td colspan="2">To Protect the Jacket From over Pressure Condition</td></tr>
<tr><td>20</td><td>¾” BSP</td><td colspan="2">To Protect the Chamber From over Pressure Condition</td></tr>
<tr><td colspan="4"></td></tr>
</table>

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

<table>
<tr><th>CRITICAL VARIABLE</th><th>ACCEPTANCE CRITERIA</th><th>REFFERENCE</th></tr>
<tr><td>Steam Trap
(12, 24)
Refer P & I diagram:
22-3-1453</td><td>Make : Forbes Marshall
Model : SOFT31-O
Type : Float Type
Material : Cast Iron
End Connection : Threaded
Qty : 2 Nos
<table>
<tr><th>Part No.</th><th>Size</th><th>Function</th></tr>
<tr><td>12</td><td>½” BSP</td><td>Jacket Condensate</td></tr>
<tr><td>24</td><td>½” BSP</td><td>Chamber Condensate</td></tr>
</table></td><td>Process Requirements</td></tr>
<tr><td>Pressure Switch
(17)
Refer P & I diagram:
22-3-1453</td><td>Make : Orion
Pressure Housing MOC : SS316
Range : 0.2 – 3.6 bar
End Connection : Threaded
Qty : 1 No
<table>
<tr><th>Part No.</th><th>Model</th><th>Function</th></tr>
<tr><td>17</td><td>MG H04 KS 10</td><td>To set pressure level of jacket</td></tr>
</table></td><td>Process Requirements</td></tr>
<tr><td>Pressure Switch
(20M)
Refer P & I diagram:
22-3-1453</td><td>Make : Orion
Pressure Housing MOC : SS316
Range : 0.067 – 0.213bar
End Connection : Threaded
Qty : 1 No
<table>
<tr><th>Part No.</th><th>Model</th><th>Function</th></tr>
<tr><td>20M</td><td>MG LP KS 10</td><td>To set pressure level of chamber</td></tr>
</table></td><td>Process Requirements</td></tr>
<tr><td>Pressure Switch
(30S)
Refer P & I diagram:
22-3-1453</td><td>Make : Orion
Pressure Housing MOC : SS316
Range : 0.5 – 7.0 bar
End Connection : Triclover /Threaded
Qty : 3 No
<table>
<tr><th>Part No.</th><th>Size</th><th>Function</th></tr>
</table></td><td>Process Requirements</td></tr>
</table>

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

<table>
<tr><th>CRITICAL VARIABLE</th><th colspan="3">ACCEPTANCE CRITERIA</th><th>REFFERENCE</th></tr>
<tr><td></td><td>3G</td><td>MG H07 KS 10</td><td>To Set Pressure level of Plant Water</td><td></td></tr>
<tr><td></td><td>3H</td><td>MG- H07-KT-B-0</td><td>To Set Pressure level of Pure Water</td><td></td></tr>
<tr><td></td><td>30S</td><td>MG H)& KS 10</td><td>To Set Pressure Level of Softened Water</td><td></td></tr>
<tr><td>Pressure Switch
(3I)
Refer P & I diagram:
22-3-1453</td><td colspan="3">Make : Orion
Pressure Housing MOC : SS316
Range : 0.5 – 10.0 bar
End Connection : Threaded
Qty : 1 No</td><td>Process Requirements</td></tr>
<tr><td></td><td>Part No</td><td>Model</td><td>Function</td><td></td></tr>
<tr><td></td><td>3I</td><td>MG H10 KS 10</td><td>To Set Pressure Level of Compressed Air</td><td></td></tr>
<tr><td>Non Return Valve
(29)
Refer P & I diagram:
22-3-1453</td><td colspan="3">Make : Leader
MOC : Brass
End Connection : Threaded
Qty : 1 No</td><td>Process Requirements</td></tr>
<tr><td></td><td>Part No</td><td>Size</td><td>Funtion</td><td></td></tr>
<tr><td></td><td>29</td><td>½’’ BSP</td><td>Chamber Condensate</td><td></td></tr>
</table>

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

8.2.3.1 VACUUM SYSTEM

<table>
<tr><th>CRITICAL VARIABLE</th><th>ACCEPTANCE CRITERIA</th><th>REFFERENCE</th></tr>
<tr><td>Vacuum Pump & Motor
(VP)
Refer P & I diagram:
22-3-1453</td><td>Make : New Genre
Model : LX2
Type : Watering Type
Capacity : 50 m^3/hr
Location : On Skid
HP / RPM : 3 HP/ 2850 RPM
Function : To create vacuum in the chamber.</td><td>Process Requirements</td></tr>
<tr><td>Steam Condenser
(CI)
Refer P & I diagram:
22-3-1453</td><td>Type : Shell & Tube
Transfer area : 0.24 m^2
Material : SS304
Function : To condense the exhaust steam (from Chamber) before entering the vacuum pump.</td><td>Process Requirements</td></tr>
<tr><td>Pneumatic Piston Type valve
with Solenoid
(202, 208,)
Refer P & I diagram:
22-3-1453</td><td>Make : Machinfabrik
MOC : SS316L
Type : Single Acting
End Connection : Plain End/ Threaded
Qty : 3 Nos
<table>
<tr><th>Part No</th><th>Size</th><th>Function</th></tr>
<tr><td>202</td><td>1” OD</td><td>Chamber Vacuum</td></tr>
<tr><td>208</td><td>¾” OD</td><td>Chamber Filter Air in</td></tr>
<tr><td>301</td><td>½” BSP</td><td>Vacuum Pump Softened water in</td></tr>
</table></td><td>Process Requirements</td></tr>
<tr><td>Non Return Valve
(2D)
Refer P & I diagram:
22-3-1453</td><td>Make : Leader
MOC : Brass
End Connection : Threaded
Qty : 1 No
<table>
<tr><th>Part No</th><th>Process</th><th>Function</th></tr>
</table></td><td>Process Requirements</td></tr>
</table>

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA			REFFERENCE
	2D	Process Requirements	To prevent backflow from	
Air Filter (AF) Refer P & I diagram: 22-3-1453	Make : Sartorius End Connection : 1 ½" OD TC Filter Retention : 0.2 micron Location : On Unloading Side. Function : To filter the air before entering into the Chamber			Process Requirements

8.2.3.2 ELECTRICAL CONTROL PANEL & POWER PANEL

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Type	Inbuilt	Process Requirements
Material	SS304	Process Requirements
Switch Gear	Contactor – Siemens Miniature Circuit Breaker – Siemens Over Load Relay – Siemens Indication Lamp – Mimic Terminal Block – Connectwell	Process Requirements

8.2.3.3 CONTROL INDICATION ON UNLOADING SIDE PANELLING

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Push Buttons with indication lamps	Colour coded push buttons with indication lamps are provided for the following: 1. Unloading door open. 2. Unloading door close. 3. Unloading door open acknowledge. 4. Emergency stop.	Process Requirements
Indication lamps	Colour coded indication lamps are provided for the following: 1. Door precondition indication. 2. Process on/end indication.	Process Requirements

8.2.3.4 CONTROL PANEL INDICATION ON LOADING SIDE

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
Push Buttons with indication lamps	Colour coded push buttons with indication lamps are provided for the following: 1. Loading door open. 2. Loading door close. 3. Control on/off switch. 4. Emergency stop.	Process Requirements
Indication lamps	Colour coded indication lamps are provided for the following: 1. Door precondition indication. 2. Alarm Indication.	Process Requirements
MMI	The operator interface (E 1061) is fitted onto the Control Panel on the Loading side.	Process Requirements
Printer	The Printer is fitted onto the Control Panel on the Loading side.	Process Requirements
Strip Chart Recorder	The Strip Chart Recorder is fitted onto the Control Panel on the Loading side.	Process Requirements

8.2.3.5 INSTRUMENTATION & SCADA

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
PLC Refer IBD: 24-4-1021	Make : Mitsubishi Model : FX3U 32MRES No of digital inputs : 16 Nos No of digital inputs used : 5 Nos Type of input : 24V DC No of digital outputs : 16 Nos No of digital outputs used : 10 Nos Type of output : Potential Free Relay Function : To control the process automatically.	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
. Analog I/P Card Refer IBD: 24-4-1021	Make : Mitsubishi Model : FX3U 4ADPTW ADP No of analog inputs : 4 Nos No of analog inputs used : 4 Nos Type of analog input : 4 Nos No of analog outputs used : 0 No Qty : 1 No Function : To give analog input & analog output to PLC.	Design Requirements
Analog I/P & O/P Card Refer IBD: 24-4-1021	Make : Mitsubishi Model : FX3U 3A ADP No of analog inputs : 2 Nos No of analog inputs used : 2 Nos Type of analog input : 4-20 mA Qty : 1 No Function : To give analog input & anlog Output to PLC.	Design Requirements
Communication Card Refer IBD: 24-4-1021	Make: Mitsubishi Model : FX3U 232BD	Design Requirements
MMI Refer IBD: 24-4-1021	Make: Mitsubishi (Beijer Electronics) Model : E 1061 Printer Port : Rs 232 Function : To start the process & display online parameters	Design Requirements
Printer Refer IBD: 24-4-1021	Make : Epson Model : LX 310 Function : To print online parameters.	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
D.C. Source Refer IBD: 24-4-1021	Make : Shavison Model : G31 – 60 – 24 Type : SMPS I/P Voltage : 230V AC O/P Voltage : 24 V DC, 2.5 A Function: To provide 24 V DC, 2.5 A supply to PLC	Design Requirements
Temperature Transmitter Refer IBD: 24-4-1021	Make : Radix Range : 0 to 200^{0}C Accuracy : ± 0.1% of FS I/P : Pt 100 O/P : 4 – 20 mA Qty. : 1 No Function: To convert temperature input to 4-20 mA	Design Requirements
Pressure Transmitter (2E) Refer IBD: 24-4-1021	Make : Jumo Range : 0 to 4 bar (A) {-1 to 3 bar(g)} Accuracy : 0.25% O/P : 4 -20 mA End Connection : ½” BSP Qty : 1 No Function: To convert pressure input to 4–20 mA.	Design Requirements
Temperature Sensor Refer IBD: 24-4-1021	Make : Radix Type : Pt100/ Duplex/ 3 Wire/ Flexible Size : 6 mm Tip Dia X 2“ Long Cable Length : 5 Meter Long Accuracy : Class A Qty : 4 Nos Location: Inside the chamber.	Design Requirements
Temperature Sensor Refer IBD: 24-4-1021	Make : Radix Type : Pt100/ Duplex/ 3 Wire/ Fixed Size : 6 mm Tip Dia X 4“ Long Accuracy : Class A	Design Requirements

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

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
	Qty : 1 No Location: Chamber Condensate.	
. Strip Chart Recorder Refer IBD: 24-4-1021	Make : Yokogawa No of Channels : Six No & Type of Inputs : 5T + 1P Temperature: 5 Nos Range : 0 to 200^0C Pressure : 1 No, 4 - 20 mA Range: -1 to 3 bar	Design Requirements
Shelves Refer Shelves Diagram 30- 3-587	Material : SS316 L Pattern : Perforated Type : Half Layer :2 Nos Equispased Qty : 4 Nos	Design Requirements

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

8.3 SAFETY FEATURES & ALARMS

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
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 Requirements
Door Obstruction Safety	While the door is closing, the door will retract to open if obstructed by hand or any other object.	Safety Requirements
Door/ Gasket Operation	Electro pneumatic	Safety Requirements
Door Locking System	Pneumatic through process.	Safety Requirements
Alarms	**Alarms will be on if** • 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. • 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.	Safety Requirements

	• 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.	

8.4 PROCESS DETAILS

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	REFFERENCE
AUTO MODE	The following process can be performed automatically through **PLC:** 1. Vacuum Leak Test – 1 2. Vacuum Leak Test (HOT) - 2 3. Warm Up Cycle – 3 4. Bowie and Dick Test – 4 5. Standard Process (Gravity Displacement Program) – 5 & 6 6. HPHV Process (Pre Vacuum Program with Vacuum Drying) – 7, 8, 9, 10 & 11 Programmed Parameters: Set through Man Machine Interface Parameter Change: Password Protected. (3 Level Password Protection for E 1061)	Process Requirements

MANUAL MODE	The above-mentioned processes can be performed manually with rocker switch, temperature indicator cum controller and Compound gauges.	Process Requirements

8.4.1 DIGITAL INPUT DETAILS

S.No.	INPUT NAME	POSITION	REFFERENCE
1.	DOOR PRECONDITION	X0	Process Requirements
2.	JACKET PRESSURE	X1	Process Requirements
3.	NOT USED	X2	Process Requirements
4.	NOT USED	X3	Process Requirements
5.	NOT USED	X4	Process Requirements
6.	NOT USED	X5	Process Requirements
7.	VACUUM PUMP TRIP	X6	Process Requirements
8.	UNOADING DOOR ACKNOWLEDGE	X7	Process Requirements
9.	EMERGENCY STOP	X10	Process Requirements
10.	NOT USED	X11	Process Requirements
11.	SPARE	X12	Process Requirements
12.	SPARE	X13	Process Requirements
13.	SPARE	X14	Process Requirements
14.	SPARE	X15	Process Requirements

8.4.2 PROCESS PHASE:

PROCESS/PHASE	PARAMETER NAME (MMI)	UNIT
WARM UP CYCLE-3	PRE VACUUM	X.XXX BAR
	WARM UP TEMP	XXX.X DEG.C
	WARM UP HOLD	XX MIN
	POST VACUUM START PRESSURE	X.XXX BAR
	POST VACUUM	X.XXX BAR
	POST VACUUM HOLD TIME	XX MIN
	PROCESS END PRESSURE	X.XXX BAR
BOWIE & DICK TEST-4	PRE VACUUM	X.XXX BAR
	PRE PRESSURE	X.XXX BAR
	NO OF PRE PULSES	XX NOS
	PRE PRESSURE UP	X.XXX BAR
	PRE PRESSURE DOWN	X.XXX BAR
	NO OF PULSES	XX NOS
	PRE PRESSURE DOWN FINAL	X.XXX BAR
	SMALL VALVE SET POIINT	XXX.X DEG.C
	STER HOLD TEMP	XXX.X DEG.C
	STER HOLD TIME	XXX SEC
	TEMP CONTROL BAND	X.X DEG.C
	OVERSHOOT TEMP	XXX.X DEG.C
	STER STOP TEMP	XXX.X DEG.C
	STER RESET TEMP	XXX.X DEG.C
	PROCESS END DELAY TIME	XX MIN
	PROCESS END PRESSURE	X.XXX BAR
	PROCESS END PRESSURE	
STANDARD PROCESS WITH SLOW & FAST EXHAUST– 5 & 6	PRE VACUUM	X.XXX BAR
	PRE PRESSURE	X.XXX BAR
	NO OF PRE PULSES	XX NOS
	PRE PRESSURE UP	X.XXX BAR
	PRE PRESSURE DOWN	X.XXX BAR

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

	NO OF PULSES	XX NOS
	PRE PRESSURE DOWN FINAL	X.XXX BAR
	SMALL VALVE SET POIINT	XXX.X DEG.C
	STER HOLD TEMP	XXX.X DEG.C
	STER HOLD TIME	XXX MIN
	TEMP CONTROL BAND	X.X DEG.C
	OVERSHOOT TEMP	XXX.X DEG.C
	STER STOP TEMP	XXX.X DEG.C
	STER RESET TEMP	XXX.X DEG.C
	PROCESS END DELAY TIME	XX MIN
	PROCESS END PRESSURE	X.XXX BAR
HIGH PRESSURE HIGH VACUUM (PRE VACUUM PROGRAM WITH VACUUM DRYING) – 7, 8, 9, 10 & 11	PRE VACUUM	X.XXX BAR
	PRE PRESSURE	X.XXX BAR
	NO OF PRE PULSES	XX NOS
	PRE PRESSURE UP	X.XXX BAR
	PRE PRESSURE DOWN	X.XXX BAR
	NO OF PULSES	XX NOS
	PRE PRESSURE DOWN FINAL	X.XXX BAR
	SMALL VALVE SET POIINT	XXX.X DEG.C
	STER HOLD TEMP	XXX.X DEG.C
	STER HOLD TIME	XXX MIN
	TEMP CONTROL BAND	X.X DEG.C
	OVERSHOOT TEMP	XXX.X DEG.C
	STER STOP TEMP	XXX.X DEG.C
	STER RESET TEMP	XXX.X DEG.C
	POST VACUUM START PRESSURE	X.XXX BAR
	POST VACUUM	X.XXX BAR
	POST VACUUM HOLD TIME	XXX MIN
	POST PRESSURE	X.XXX BAR
	NO OF POST PULSES	XXX NOS
	PROCESS END PRESSURE	X.XXX BAR

8.4.3 CALCULATION FOR F_0 VALUE

The following mathematical Expression allows the calculation of F_0

$$F_0 = \Sigma\ 10^{(T-121)/z}\ \Delta t$$

Where

1. F_0 = F_0 Value
2. T = Average Temperature
3. z = Value which indicates relationship of lethality to temperature
   = 10^0C (assumed)
4. 121^0C = Sterilization Temperature

Example : Calculation of F_0 Value at T = 119^0C

$$F_0 = \Sigma 10^{(119-121)/10}\ \Delta t$$

$$= 0.630957$$

8.5 UTILITY DETAILS:

	Plant Steam for Jacket	Pure Steam for Chamber	Compressed Air	Softened Water For Vacuum System
Peak Demand	0.40 kg/min	0.58 kg/min	0.2 m^3/hr	7 lpm for 35 min cycle
Cycle Demand	4.32 kg/cycle	17.28 kg/cycle	--	--
Pressure	1.5 kg/cm^2 (g)	1.2 – 1.4 kg/cm^2 (g)	6-7 kg/cm^2 (g)	1.2 kg/cm^2 (g)
Quality	Dry & Saturated	Dry & Saturated	Lubricated & Moisture free	Softened Water, less than 25^0C
Line Size	½’ NB	¾” OD	½” NB	½” NB
End Connection	Triclover	Triclover	Triclover	Triclover

Equipment Drain (Drain Pipe for Equipment by MF) : 2” NB

Floor drain (provided by customer) : 4” NB

Electricity **Power** **:** 415V – 3PH – 50Hz AC, 4 Wire Supply

Control **:** 230V – 1PH – 50Hz Stabilized AC Supply

Connected Load **Resistive Load** **:** NA

Inductive Load **:** 3 HP

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

Incoming electric cable size: 4 Core x 2.5 Sq.mm Copper cable or
4 Core x 2.5 Sq.mm Aluminum cable

Weight of Equipment without load: 1650 Kg

8.6 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
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

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

S.No.	Parts name	Material of Construction
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
31.	Stand Material	SS304
32.	Skid Material	SS304
33.	Rail Pipe Material	SS316L
34.	Steam Baffle Material	SS316L

Checked By
(Engineering)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

……

……

……

……

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

8.7 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.

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

……

……

……

……

……

……

……

……

……

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

11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

……

……

……

……

……

……

……

……

……

12.0 RECOMMENDATION:

……

……

……

……

……

……

……

13.0 ABBREVIATIONS:

AC	:	Alternate Current
BSP	:	British Standard for Pipe Threading
CI	:	Cast Iron
cGMP	:	Current Good Manufacturing Practice
cm^2	:	centimeter square
D	:	Depth
db	:	Decibel
DC	:	Direct current
DQ	:	Design Qualification
GA	:	General Arrangement
H	:	Height
HPHV	:	High Pressure High Vacuum
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
I/P	:	Input
ID	:	Inner Diameter
Kg	:	Kilogram
Ltd.	:	limited
MCB	:	Miniature Circuit Breaker
Min	:	Minute
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
NB	:	Nominal Bore
No.	:	Number
O/P	:	Output
OD	:	Outer Diameter
P & ID	:	Piping and Instrumentation Diagram
PDQ	:	Protocol design qualification
PLC	:	Programmable Logic Controller

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

PO	:	Purchase Order
PVT.	:	Private
RH	:	Relative Humidity
RPM	:	Revolution per Minute
RTD	:	Resistance Temperature Detector
SMPS	:	Switched Mode Power Supply
SS	:	Stainless Steel
TC	:	Triclover
Temp.	:	Temperature
URS	:	User Requirement Specification
V	:	Volt
W	:	Width

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

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			