



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
SPRAY STERILIZER**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
SUPER HEATED WATER SPRAY  
STERILIZER**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Loading Area</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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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 Super-Heated Water Spray 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 Super-Heated Water Spray sterilizer (**Make: MACHIN FABRIK**) to be installed in the **Loading Area**.
- 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:

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



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- Post Approval of Qualification Protocol after Execution.

**5.0 EQUIPMENT DETAILS:**

<b>Equipment</b>	Super Heated Water Spray Sterilizer
<b>Id number</b>	
<b>Size</b>	1750 DIA X 4500 LG mm
<b>Chamber volume</b>	10800 Liters
<b>Working temperature</b>	Up to 134 <sup>0</sup> C
<b>Serial number</b>	
<b>Job number</b>	
<b>Loaction</b>	Loading Area

**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 Super Heated Water Spray Sterilizer has been an unique Sterilization System offered by **M/s. Machin fabrik Industries Pvt. Ltd.** as it can be efficiently used to perform the sterilization of polypropylene bags by heating water above 100 Deg C and still maintaining it in liquid phase.

**6.1 STERILIZATION MECHANISM :**

- Steam is introduced in the tube side of the heat exchanger.
- The water is heated up gradually, by circulating it through the heat exchanger.
- The chamber is pressurized gradually by introducing compressed air.
- As the temperature of water in the chamber increases and reaches the sterilization temperature, the control system in place controls this temperature for the sterilization period.

When the sterilization hold period is over, the circulating water is cooled by introducing cooling water.

through the tubes of the heat exchanger

When the chamber reaches room temperature, the sterilized charge is then unloaded in the sterile area.

Thus, Super-Heated Water Spray Sterilizer process is made up of three phases viz:-

- a) Heat Up
- b) Sterilization Hold
- c) Cooling



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**6.2 UTILITY CONNECTIONS**

**6.2.1 Plant Steam for HE**

- Dry & saturated plant steam at a pressure of 3-6 Bar with a line of size 3” NB, Flanged End Connection.

**6.2.2 Cooling Water**

- Cooling water at a pressure of 4-6 Bar with a line of size 3” NB, Flanged End Connection.

**6.2.3 Compressed Air**

- Dry & Lubricated compressed air at a pressure of 6-7 Bar with a line of size ½” NB, Flanged End Connection.

**6.2.4 Process Air**

- Sterile & oil free compressed air at a pressure of 3-4 Bar with a line of line size 1” NB Flanged End Connection.

**6.2.5 Process Water (Purified)**

- Purified Water at a pressure of 2-3 Bar with a line of a 2” NB Flanged End.

**6.2.6 Soften Water**

- Soften water at a pressure of 1.5 kg/cm<sup>2</sup> (g) with a line of size ¾” NB, Flanged End Connection.

**6.2.7 Drain Manifold**

- Line of size 6” dia

**6.2.8 Electricity**

- 415 V – 3 PH – 4 Wire, 50 HZ with neutral & earthing suitable for 23 HP connect this with control panel.

**6.3 GENERAL INSTRUCTIONS FOR UTILITY CONNECTIONS:**

Piping and electrical wiring should comply with good installation practices.

The diameter of service pipe work should in many cases be oversized when compared to the size of the appropriate sterilizer pipe connection in order not to cause an undesired pressure drop. The size of each specific supply pipe should be calculated with regard to peak flow and pipe length. The maximum consumption figures will be found on a Utility Details Sheet (as per Design Qualification of this package).



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Pipes, which are running to the service area prior to installation of the sterilizer, should be located and terminated so that they will not interfere with the positioning of the sterilizer. The pipes should be terminated with shut off valves. The pipes should be connected after positioning of the sterilizer. Flush all the Utility pipes before connecting to the sterilizer.

Install shut-off valves & pressure gauges in the Utility supply line as close to the equipment as possible to allow isolation of the supply to each individual item of equipment without interfering with other equipments installed in the main building supply.

Insulate all the hot Utility pipes.

Clearly identify service pipes and electrical wiring.

### **6.4 PRACTICAL ARRANGEMENTS**

- Connect the sterilizer to a main steam line, not to an inadequately drained or inadequately vented “dead leg”. Long branch connections to sterilizers should be avoided.
- If several autoclaves are connected to the same pipe consideration must be taken as to what extent the autoclaves will require steam simultaneously.
- The steam supply pipes should fall towards the sterilizer minimum gradient 1:50.
- The steam pressure upstream of the reducing valve should not fluctuate by more than 10%.
- No other large steam consumers other than autoclaves should be piped downstream of the reducing valve.
- Branch pipes should be connected from the top of the horizontal main pipe.  
A connection should be provided on the steam supply line adjacent to the sterilizer to enable steam sampling to be undertaken to check for the presence of non-condensable gases.
- Because of its daily use, the shut off valve should be of the easy – to – use type.





## **INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER**

### **6.5 CONSTRUCTIONAL FEATURES**

The **Super-Heated Water Spray Sterilizer** is sub – grouped in 8 parts.

They are as follows :

- Pressure vessel
- Mounting and panelling arrangement
- Insulation
- Door assembly
- Piping & piping accessories
- Indication, monitoring and control features
- Automation system
- Handling accessories

### **6.6 PRESSURE VESSEL**

The pressure vessel is sub grouped in two parts. They are as follows:

- Chamber
- Air pocket

#### **6.6.1 CHAMBER:**

- i) The chamber is made up of 6 mm thick Stainless Steel 316L plates having a surface finish of  $R_a \leq 1.0 \mu\text{m}$ .
- ii) The Chamber is designed to withstand a working pressure of  $2.5 \text{ kg/cm}^2$  (g) and working temperature of  $134^\circ\text{C}$ . The chamber is reinforced with Stainless Steel channel made up of 6 mm thick.

#### **6.6.2 AIR POCKET:**

- i) The Air Pocket is made up of 5 mm thick Stainless Steel 304.
- ii) The Air Pocket is designed to withstand a working pressure of  $3.0$  to  $3.5 \text{ kg/cm}^2$  (g)
- iii) Door sealing is actuated by a silicone gasket, which is pressurized by compressed Air from **AIR POCKET**. For door retraction, the gasket is retracted by creating a Vacuum in the **AIR POCKET** With the help of an ejector.



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### **6.7 MOUNTING & PANELLING ARRANGEMENT**

- i) The pressure vessel is mounted on a saddle made up of SS channels.
- ii) Panelling on all loading & unloading sides are provided. The paneling is made up of Stainless Steel 304 Sheets having surface finish  $R_a < 1\mu\text{m}$ .

### **6.8 INSULATION**

- i) The pressure vessel is provided with 75 mm thick insulation of R.B. Glass Wool.
- ii) The insulation is covered with 0.558 mm (24G) Aluminum sheet outer cover.

### **6.9 DOOR ASSEMBLY**

- i) The sterilizer chamber is provided with two, Horizontal sliding doors.
- ii) The door is made up of 25 mm thick Mild Steel & 6 mm thick Stainless steel 316 L plate having finish  $R_a \leq 1.0\mu\text{m}$ . sandwiched with Mild Steel plate.
- iii) The door moves with the support of two horizontal extensions.
- iv) The sliding of the door is effected with help of a double acting pneumatic cylinder.
- v) The bearing assembly provided ensures smooth and frictionless movement of door.
- vi) The door pneumatic cylinder is provided with flow control valve which aid in adjusting the speed of door movement.
- vii) Door sealing is actuated by a silicone gasket which is pressurised by compressed Air from air pocket. For door retraction, the gasket is retracted by creating a Vacuum in the air pocket with the help of an ejector.

### **6.10 PIPING & PIPING ACCESSORIES**

- i) The piping provided for all the utilities is of Stainless Steel 316L.
- ii) The piping is full argon welded and provided with sanitary type flanged end connections.
- iii) The control valves which are in direct contact with chamber are Stainless Steel 316L (contact parts).

### **6.11 INDICATING, MONITORING & RECORDING SYSTEM**

- i) The critical parameters of a sterilizer are Temperature and Pressure.
- ii) There are various indicating, monitoring and control devices, which are listed with respect to



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there place of installation and significance in the system are given along with the respective diagram descriptions attached in the next part of this section.

### **6.12 AUTOMATION SYSTEM**

- i) The heart of the automation system is a Programmable Logic Controller (PLC).
- ii) The entire control system is actuated by the PLC.
- iii) It also ensures proper inputs and outputs simulation.
- iv) The Man Machine Interface (MMI) located on the front fascia of the control panel displays the process data, Temperature & Pressure values.

### **6.13 OPENING OF THE LOADING DOOR**

First select Door Gasket Pressurization/Retraction Rotary Switch to door gasket retraction mode.

- The door gasket will retract due to actuation of **SLV** & Rotary Actuator Ball Valve **508 & 511**. Vacuum is created in air pocket with the help of ejector (**55**).
- As soon as vacuum level reaches to the set value in vacuum switch, the gasket retraction will stop.
- Press push to open push button (**09**) provided on locking side control panel.
- As soon as open push button is pressed, actuates the door cylinder SLV (**504**) & flow control valve (**FC3**).
- The door will completely open.

### **6.14 CLOSING OF THE LOADING DOOR**

Press **Push to Close** push button (**10**) present on the control panel.

- The door cylinder slides by actuation of SLV and flow control valve (**FC4**).
- This limit switch (**LS3-5F**) is pressed.
- Select door Gasket Pressurization/Retraction Rotary switch to door gasket pressurization mode, which pressurizes the door gasket.
- The gasket is pressurized up to the set value in the pressure switch (**57**).
- The pressure switch turns 'ON' the Door Precondition indication.

### **6.15 OPENING OF UNLOADING DOOR**

- If the sterilization process is successfully completed then only you can open the Unloading side door.
- The door gasket will retract due to actuation of **SLV** & Rotary Actuator Ball Valve **506 & 511**.
- Vacuum is created in air pocket with the help of ejector (**55**).



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- As soon as vacuum level reaches to the set value in vacuum switch, the gasket retraction will stop.
- Press push to open push button **(03)** provided on locking side control panel.
- As soon as open push button is pressed, actuates the door cylinder SLV **(502)** & flow control valve **(FC1)**
- The door will completely open.

### **6.16 CLOSING OF UNLOADING DOOR**

- Press **Push to close** push button **(04)** present on the control panel.
- The door cylinder slides by actuation of SLV **(501)** and flow control valve **(FC2)**.
- This limit switch **(LS1-5E)** is pressed.
- Turn door gasket press / retraction Rotary switch to door gasket press mode, which pressurizes the door gasket.
- The gasket is pressurized up to the set value in the pressure switch **(56)**.
- The pressure switch turns 'ON' the Door Precondition indicatio

### **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:**

<b>INSTALLATION CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION (COMPLIES/ NOT COMPLIES )</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Grouting and Mounting</b>	Should be properly grouted and mounted.		
<b>Leveling</b>	Should be properly balanced and leveled.		
<b>Edges of parts</b>	Metal parts should be properly ground without any sharp edges.		
<b>Welding of Joints</b>	Welding of joints should be without any welding burrs.		
<b>Place of Installation</b>	Loading Area 'L' Block.		
<b>Room Condition</b>	General Room Conditions.		
<b>Illumination</b>	NLT 300 Lux		
<b>Working space around the Equipment.</b>	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

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

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

**Inference:**

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**Reviewed By**  
**(Manager QA)**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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Sign/Date: .....

**8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

Critical Variable	Acceptance Criteria			Observation (Complies /Non Complies)
	Plant Steam for H/E	Process Water (Purified)	Process Air	
Peak Demand	35 kg/min	---	7.0 m <sup>3</sup> /min	
Cycle Demand	600 kg/cycle	1000 liter/change	9.0 m <sup>3</sup> /cycle	
Pressure	3 to 6 bar	2 to 3 bar	3 to 4 bar	
Quality	Dry & Saturated	Purified Water	Sterile & Oil Free	
Line Size	3" NB	2" NB	1" NB	
End Connection	Flange	Flange	Flange	

Critical Variable	Acceptance Criteria			Observation (Complies /Non Complies)
	Compressed Air	Cooling Water	Softened Water	
Peak Demand	0.2 m <sup>3</sup> /hr	400 lpm	25 liter/min	
Cycle Demand	---	6000 liter/cycle	---	
Pressure	6 – 7 bar	4 – 6 bar	1.5 bar	
Quality	Dry & Lubricated	Cooling Water	Softened Water	
Line Size	½" NB	3" NB	¾" NB	
End Connection	Flange	Flange	Flange	

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(Quality Assurance)  
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**8.3 WORKING CONDITION AND TEST PARAMETER**

Critical Variables	Acceptance criteria				Observation (Complies /Non Complies)
	Chamber	Shell	Tube	Air pocket	
Working pressure	2.5 kg/cm <sup>2</sup> (g)	3.0 kg/cm <sup>2</sup> (g)	6.0 kg/cm <sup>2</sup> (g)	3.0 kg/cm <sup>2</sup> (g)	
Hydro test pressure	3.75 kg/cm <sup>2</sup> (g)	4.5 kg/cm <sup>2</sup> (g)	9.0 kg/cm <sup>2</sup> (g)	N.A.	
Working temperature	134 <sup>0</sup> C	142 <sup>0</sup> C	152 <sup>0</sup> C	60 <sup>0</sup> C	
Vacuum	Full	N.A.	N.A.	Partial	
Pneumatic test	N.A.	N.A.	N.A.	4.5 kg/cm <sup>2</sup> (g)	

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





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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**8.4 VERIFICATION OF TECHNICAL SPECIFICATION :**

**8.4.1 SHELL DESIGN**

**8.4.1.1 CONSTRUCTIONAL DETAILS**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Size	1750 Dia X 4500 Lg (mm)		
Chamber Opening	1200 (W) X 1200 (H) X 4500 (L) mm		
Plate Thickness	6 mm		
Material	SS316L		
Finish	Ra ≤ 1.0 μm		
Design Code	ASME SEC VIII DIV -1		
Welding Joint Radiography	10 % of Weld Length		
<b>AIR POCKET</b>			
Plate Thickness	5 mm		
Material	SS304		

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



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**8.4.1.2 SHELL INSULATION**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
<b>Material</b>	Resin Bonded Glass Wool		
<b>Thickness</b>	75 mm		
<b>Skin Temperature (Average)</b>	55 <sup>0</sup> C (Subjected to room temperature 23 ± 2 <sup>0</sup> C)		
<b>Cover Material</b>	SS304		
<b>Cover Thickness</b>	0.558 mm (24G)		

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

**Inference:**

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**8.4.1.3 SADDLE**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Material	Mild Steel		
Mounting	Pit Mounted		

**8.4.1.4 RAIL & BAFFLES**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Rail Pipe Material	SS316L SS316L		
Sprinkling Tray Material	SS316L		
Piping Material of Chamber	SS316L		
Piping Material of Heat Exchanger	SS304		
Validation Port with Dummy Adaptor	MOC : SS316 No of Probes in Each Port : 8 Nos Qty : 2 Nos		

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Sign/Date: .....**

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

**Inference:**

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



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**8.4.2 .DOOR & DOOR COMPONENTS**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
<b>DOOR</b>			
Type	Horizontal Sliding		
Quantity	Two		
Material	SS316L		
Finish	Ra ≤ 1.0 μm		
<b>Door Insulation</b>			
Material	Resin Bonded Glasswool		
Thickness	100 mm		
Outer Cover Material	SS304		
Outer Cover Material Thickness	1.25 mm (18G)		
<b>DOOR COMPONENTS</b>			
Door Component Material	SS304		
Door Extension Material	SS304		
Door Operating Cylinder (5A, 5B) Refer Pneumatic Diagram: 25-3-1231	Make : Janatics Mounting : Horizontal Type : Double Acting Size : 63 Bore X 1310 Stroke Qty : 2 Nos Function : Door Operation.		
Solenoid Valves for Door Operating Cylinder (501, 502 & 503, 504)	Make : Festo Model : JMFH - 5 ¼, Double coil Pneumatic Pressure : 1.5 –		



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## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE						
Refer Pneumatic Diagram: 25-3-1231	8.0 Bar Coil supply : 1PH – 230V – 50Hz Qty : 2 Nos Function : To operate the door cylinders.								
Rotary Actuated Pneumatic Ball Valve with Solenoid (507, 508, 511) Refer Pneumatic Diagram: 25-3-1231	Make : Micro Pneumatics/ President Type : Double acting MOC : SS304 End connection: Threaded								
	<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 30%;">Part No.</th> <th>Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">507</td> <td rowspan="3">Gasket Pressurization/ Retraction</td> </tr> <tr> <td style="text-align: center;">508</td> </tr> <tr> <td style="text-align: center;">511</td> </tr> </tbody> </table>	Part No.	Function	507	Gasket Pressurization/ Retraction	508	511		
Part No.	Function								
507	Gasket Pressurization/ Retraction								
508									
511									
Pressure Switch (57) Refer Pneumatic Diagram: 25-3-1231	Make : Orion Model : MG H04 KS 10 Range : 0.2 – 3.6 bar Quantity : 1 No Function : To set the pressure level for the gasket.								
Vacuum Switch (58) Refer Pneumatic Diagram: 25-3-1231	Make : Orion Model : MG V00 KA 10 Range : 760 mm to 100 mm of Hg (Vacuum) Quantity : 1 No Function : To set the vacuum level for the gasket.								
Compound Gauges	Make : Forbes Marshall								



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE						
(53, 54) Refer Pneumatic Diagram: 25-3-1231	Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm <sup>2</sup> MOC : SS316 for Contact Part SS304 for Non Contact Part Accuracy : ± 1% FS Qty : 2 Nos Connection : 3/8" BSP, Back Connection Function : Indication of gasket pressure.								
. Filter Regulator Lubricator (5I) Refer Pneumatic Diagram: 25-3-1231	Make : Janatics/ Rotex Size : ¼" BSP Range : 0.5 to 10 Bar Dial size : 2" Dial with 1/8" BSP Function : To filter, regulate & lubricate the incoming compressed air.								
Regulator (5J, 5K) Refer Pneumatic Diagram: 25-3-1231	Make : Janatics Range : 0.5 to 10 Bar Dial Size : 2" Dial with 1/8" BSP Qty : 2 Nos End Connection : Threaded								
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Part No.</th> <th style="width: 25%;">Size</th> <th style="width: 50%;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">5J</td> <td style="text-align: center;">¼"</td> <td style="text-align: center;">Door</td> </tr> </tbody> </table>	Part No.	Size	Function	5J	¼"	Door		
Part No.	Size	Function							
5J	¼"	Door							



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## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
		BSP	Operation		
	5K	½"	Gasket		
		BSP	Pressurization / Retraction		
Ejector Refer Pneumatic Diagram: 25-3-1231	Make : Unique Size : ½" X ¾" Qty : 1 No Function : To retract door gasket before opening door.				
Ejector Refer Pneumatic Diagram: 25-3-1231	Make : Unique Size : ½" X ¾" Qty : 1 No Function : To retract door gasket before opening door.				
. Limit Switch (5E, 5F) Refer Pneumatic Diagram : 25-3-1231	Make : Bohmen Model : 1 NO + 1 NC Type : MLRLS Qty : 2 Nos Function : Sensing the door position.				
.Photocell Sensor	Make : P & F/ Optex Type : Single Path Model : M100/MV100-RT/76a/103/115 Qty : 2 Sets Function : Door obstruction safety.				



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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**8.4.3 PANELLING**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Panelling	Only front paneling (As per layout)		
Material	SS304		
Finish	$Ra \leq 1.0 \mu m$		
Mounting	Pit Mounted		

**8.4.4 WATER RECIRCULATION SYSTEM**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Transfer Tank Refer P & I Diagram: 22-3-1452	MOC : SS316L Capacity : 1200 Liters Function : To hold the process during leak testing.		
Transfer Pump (TP) Refer P & I Diagram: 22-3-1452	Make : Superflow/ Flowchem MOC : SS316 Capacity : 15 m <sup>3</sup> /hr at 20 meter head Qty : 1 No Function : Water Transfer to transfer tank.		





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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
5.5.3. Motor for Transfer Pump	Make : Crompton/ Kirloskar/ LHP Type : Foot Mounted HP/RPM : 3 HP/ 2800 RPM Qty : 1 No		
Circulating Pump (CP) Refer P & I Diagram No : 22-3-1452	Make : Superflow/ Flowchem Type : Centrifugal Capacity : 250 m <sup>3</sup> /hr Suction X Discharge : 150 X 125 MOC : SS316 Qty : 1 No Function : Chamber water circulation during process.		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE									
. Motor for Circulating Pump	Make : Crompton Type : Foot Mounted HP / RPM : 10 HP/ 960 RPM Qty : 1 No											
Heat Exchanger (HE) Refer P & I Diagram: 22-3-1452	Material of Construction: SS316L Type: Shell and Tube Type Shell Thickness : 4 mm Tube Sheet Thickness : 22 mm Heat Exchange Area : 24.9 m <sup>2</sup>											
Rotary Actuated Pneumatic Ball Valve (402, 403, 405, 406, 412) Refer P & I Diagram: 22-3-1452	Make : Micro Pneumatics/ President Type : Double Acting MOC : SS304 End Connection : Threaded											
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Part No.</th> <th style="width: 15%;">Size</th> <th style="width: 70%;">Function</th> </tr> </thead> <tbody> <tr> <td>402</td> <td>1" BSP</td> <td>H/E Plant Steam in (Small)</td> </tr> <tr> <td>403</td> <td>1 1/2" BSP</td> <td>H/E Cooling Water in (Small)</td> </tr> </tbody> </table>	Part No.	Size	Function	402	1" BSP	H/E Plant Steam in (Small)	403	1 1/2" BSP	H/E Cooling Water in (Small)		
Part No.	Size	Function										
402	1" BSP	H/E Plant Steam in (Small)										
403	1 1/2" BSP	H/E Cooling Water in (Small)										



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	405	1 ½” BSP	H/E Condensate Out		
	406	1” BSP	H/E Exhaust		
	412	½” BSP	H/E Vent Valve		
Rotary Actuated Pneumatic Butterfly Valves (401, 404, 409, 407) Refer P & I Diagram: 22-3-1452	Make : Micro Pneumatics/ President Type : Double Acting MOC : SS304 End Connection : Flanged				
Part No.	Size	Function			
401	3”	H/E Plant Steam in (Big)			
404	2 ½”	H/E Cooling Water in (Big)			
409	3 ”	H/E Main Plant Steam in			



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	407	3"	H/E Cooling Water Out		
Solenoid Valves for Rotary Actuated Pneumatic Ball Valve & Butterfly Valve (401, 402, 403, 404, 405, 406, 407, 409, 412) Refer Pneumatic Diagram: 25-3-1231 <b>Note: Common            Solenoid Valve for            403/407</b>	Make : Festo Model : MFH - 5¼, Single Coil Pneumatic Pressure : Max 0.5 – 8.0 Bar Coil Supply : 1PH – 230V – 50Hz Qty : 8 Nos Function : To operate Rotary Actuated Pneumatic Ball Valves & Rotary Actuated Pneumatic Butterfly Valves.				
. Manual Ball Valve (4403, 4408) Refer P & I Diagram: 22-3-1452	Make : President Type : 3 PC Design MOC : SS304 End Connection : Threaded				
	Part No.	Size	Function		
	4403	1 ½" BSP	H/E Cooling Water in (Small)		
	4408	¾" BSP	H/E Drain		



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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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**8.4.5 ELECTRICAL CONTROL PANEL & POWER PANEL**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Type	Stand Alone		
Material	SS304		
Switch Gear	Contactora – Siemens Miniature Circuit Breaker – Siemens Over Load Relay – Siemens Indication Lamp – Siemens Terminal Block – Elmex/ Connectwell		

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

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

**Inference:**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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**8.4.5.1 CONTROL INDICATION ON UNLOADING SIDE:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Push Buttons with indication lamps	Colour coded push buttons with indication lamps are provided for the following : <ol style="list-style-type: none"><li>1. Unloading door open.</li><li>2. Unloading door close.</li><li>3. Emergency stop.</li></ol>		
Indication lamps	Colour coded indication lamps are provided for the following : <ol style="list-style-type: none"><li>1. Door precondition indication.</li><li>2. Process on/end indication.</li></ol>		

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

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

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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**CONTROL PANEL ON LOADING SIDE**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Push Buttons with indication lamps	Colour coded push buttons with indication lamps are provided for the following: <ol style="list-style-type: none"><li>1. Emergency stop.</li><li>2. Control on/off switch.</li><li>3. Purified Water In &amp; Spray Pattern On/Off Switch.</li><li>4. Door gasket pressuring &amp; retraction on/off switch.</li><li>5. Loading door open.</li><li>6. Loading door close.</li></ol>		
Indication lamps	Colour coded indication lamps are provided for the following: <ol style="list-style-type: none"><li>1. Alarm indication</li><li>2. Door precondition Indication.</li></ol>		
MMI	The operator interface (E 1061) is fitted onto the Control Panel on the Loading side.		
Printer	The Printer is fitted onto the Control Panel on the Loading side.		
Strip Chart Recorder	The Strip Chart Recorder is fitted onto the Control Panel on the Loading side.		







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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE						
Solenoid Valves for Rotary Actuated Pneumatic Ball Valves (205, 206, 217, 219, 217A, 217B, 219A, 219B)  Refer Pneumatic Diagram: 25-3-1231  <b>Note : Common Solenoid Valve for Valve 217A &amp; 217B, 219A &amp; 219B</b>	Make : Festo  Model : MFH - 5¼, Single Coil  Coil Supply : 1PH – 230V – 50Hz  Qty : 6 Nos  Function : To operate Rotary Actuated Pneumatic Ball Valves.								
Manual Ball Valve (2219)  Refer P & I Diagram: 22-3-1452	Make : President  Type : 3 PC Design  MOC : SS304  End Connection : Threaded <table border="1" style="width: 100%; margin-top: 5px;"> <thead> <tr> <th style="width: 25%;">Part No.</th> <th style="width: 25%;">Size</th> <th style="width: 50%;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2219</td> <td style="text-align: center;">1 ½” BSP</td> <td style="text-align: center;">Transfer Tank Drain</td> </tr> </tbody> </table>	Part No.	Size	Function	2219	1 ½” BSP	Transfer Tank Drain		
Part No.	Size	Function							
2219	1 ½” BSP	Transfer Tank Drain							
Safety Valve (20)  Refer P & I Diagram: 22-3-1452	Make : Spirax Marshall  Type : Spring Loaded  MOC : Cast Iron  Range : 15 to 35 psi  End Connection : Threaded <table border="1" style="width: 100%; margin-top: 5px;"> <thead> <tr> <th style="width: 25%;">Part No.</th> <th style="width: 25%;">Size</th> <th style="width: 50%;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"> </td> <td style="text-align: center;"> </td> <td style="text-align: center;"> </td> </tr> </tbody> </table>	Part No.	Size	Function					
Part No.	Size	Function							



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	20	2" X 2" NB	Chamber Safety		
Float Switch (2L/2M) Refer P & I Diagram No: 22-3-1452	Make : Mahalaxmi Type : Vertical Mounted MOC : SS316 No of Contacts : 1 NO + 1 NC Qty : 1 No				
	Part No.	Model	Function		
	2L/ 2M	VMT- EXT-120	Chamber water Level High/ Middle		
. Float Switch (2X) Refer P & I Diagram: 22-3-1452	Make : Mahalaxmi MOC : SS316 Type : Side Mounted No of Contacts : 1 NO + 1 NC Qty : 1 No				
	Part No.	Model	Function		
	2X	SMT-16- F82	Chamber Water Level Low		
Non Return Valve (25) Refer P & I Diagram No: 22-3-1452	Make : Alfa Laval MOC : SS316 End Connection : Plain End				
	Part No.	Size	Function		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	25	1 ½” OD	Chamber process air in		
. Compound Gauges (2C, 2C1) Refer P & I Diagram: 22-3-1452	Make : Forbes Marshall Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm <sup>2</sup> (g) MOC : SS316 for Contact Part SS304 for Non Contact Part Accuracy : ± 1% FS Connection : 3/8” BSP (M) Location : Loading & Unloading Side Qty : 2 Nos Function : Indication of chamber pressure.				
Regulator (20B) Refer P & I Diagram: 22-3-1452	Make : Janatics/ Rotex Range : 0.5 To 10 Bar End Connection : Threaded				
	Part No.	Size	Function		
	20B	1” BSP	To regulate the incoming process air		
Pressure Switch (20M) Refer P & I diagram: 22-3-1452	Make : Orion Pressure Housing MOC : SS316L Range : 0 – 0.25 bar End Connection : Threaded Qty : 1 No				



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	Part No.	Function		
	20M	To set pressure level of Chamber		
. Pressure Switch (3G, 3J, 3L) Refer P & I Diagram: 22-3-1452	Make : Orion Range : 0.5 – 7.0 bar End Connection : Threaded Qty : 3 Nos			
	Part No	Model	Function	
	3G	MG H07 KS 10	To set pressure level of Plant Steam	
	3J	MG H07 KS 10	To set pressure level of Cooling Water	
	3L	MG H07 KS 10	To set pressure level of Purified Water	
Pressure Switch (3I, 3K) Refer P & I Diagram:	Make : Orion Range : 0.5 – 10.0 bar End Connection : Threaded Qty : 2 Nos			



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	Part No	Model	Function		
22-3-1452	3I	MG H10 KS 10	To set pressure level of compressed air		
	3K	MG H10 KS 10	To set pressure level of Process Air		

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

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

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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**8.4.7 VACUUM SYSTEM**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE						
. Vacuum Pump & Motor (VP) Refer P & I Diagram: 22-3-1452	Make : New Genre Type : Watering Type Model : LWV-20 Location : Service floor (@ 10 mtr away) Motor : Crompton HP/ RPM : 10 HP/1440 RPM Function : To create vacuum in the chamber.								
Rotary Actuated Pneumatic Ball Valve (301) Refer P & I Diagram: 22-3-1452	Make : Micro Pneumatics/ President Type : Double Acting Moc : SS304 End Connection : Threaded <table border="1" style="width: 100%; margin-top: 5px;"> <thead> <tr> <th style="width: 20%;">Part No.</th> <th style="width: 20%;">Size</th> <th style="width: 60%;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">301</td> <td style="text-align: center;">3/4" BSP</td> <td>Vacuum pump Softened water in</td> </tr> </tbody> </table>	Part No.	Size	Function	301	3/4" BSP	Vacuum pump Softened water in		
Part No.	Size	Function							
301	3/4" BSP	Vacuum pump Softened water in							
. Rotary Actuated Pneumatic Butterfly Valve (202) Refer P & I Diagram: 22-3-1452	Make : Micro Pneumatics/ President Type : Double Acting MOC : SS316 End Connection : Flanged <table border="1" style="width: 100%; margin-top: 5px;"> <thead> <tr> <th style="width: 20%;">Part No.</th> <th style="width: 20%;">Size</th> <th style="width: 60%;">Function</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Part No.	Size	Function					
Part No.	Size	Function							



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER  
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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	202	2 ½”	Chamber Vacuum		
Solenoid Valves for Rotary Actuated Pneumatic Ball Valve & Butterfly Valve (202, 301) Refer Pneumatic Diagram: 25-3-1231 <b>Note : Common            Solenoid Valve for            Valve 202 &amp; 301.</b>	Make : Festo/ Rotex Model : MFH - 5¼, Single Coil Pneumatic Pressure : Max 0.5 – 8.0 Bar Coil Supply : 1PH – 230V – 50Hz Qty : 1 No Function : To operate Rotary Actuated Pneumatic Ball Valve & Butterfly Valve.				
Non Return Valve (2D, 2D1) Refer P & I Diagram: 22-3-1452	Make : Leader MOC : Brass End Connection : Threaded Qty : 2 Nos				
	Part No.	Size	Function		
	2D	2 ½” BSP	To prevent backflow from vacuum pump to chamber.		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA			OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	2D1	2 ½” BSP	To prevent backflow from vacuum pump to chamber.		

### 8.4.8 INSTRUMENTATION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
PLC Refer IBD: 24-3-542	Make : Mitsubishi Model : FX3U 32MRES No of digital inputs : 16 Nos No of digital inputs used :14 Nos Type of input : 24V DC No of digital outputs : 16 Nos No of digital outputs used : 16 Nos Type of output : Potential Free Relay Function : To control the process automatically.		
Extension Card (O/P card) Refer IBD: 24-3-542	Make : Mitsubishi Model : FX2N 8EYRES No of digital outputs : 8 Nos No of digital outputs used : 2 Nos Type of output : Potential		





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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
	Free Relay Function : To add additional output to PLC.		
Communication Card Refer IBD: 24-3-542	Make : Mitsubishi Model : FX3U 232BD		
. Analog Input Card Refer IBD: 24-3-542	Make : Mitsubishi Model : FX3U 4ADPTW ADP No of analog inputs : 4 Nos No of analog inputs used : 4 Nos Type of analog input : Pt 100 Qty : 1 No Function : To give analog input to PLC.		
Analog Input Card Refer IBD: 24-4-542	Make : Mitsubishi Model : FX3U 4AD ADP No of analog inputs : 4 Nos No of analog inputs used : 4 Nos Type of analog input : 4-20 mA Qty : 1 No Function : To give analog input to PLC.		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
MMI Refer IBD: 24-3-542	Make : Mitsubishi (Beijer Electronics) Model : E 1061 Printer Port : Rs 232 Function : To start the process & display online parameters.		
D.C. Source Refer IBD: 24-3-542	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.		
. Pressure Transmitter Refer IBD: 24-3-542	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 give pressure input to PLC & SCR		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION ( COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
Temperature Transmitter Refer IBD: 24-3-542	Make : Radix Range : 0 to 200 <sup>0</sup> C Accuracy : 0.1% of FS I/P : Pt 100 O/P : 4 – 20 mA Qty. : 3 Nos Function : To convert temperature input to 4 – 20mA.		
Temperature Sensor Refer IBD: 24-3-542	Make : Radix Type : Pt 100/ Duplex/ 3 Wire/ Flexible Size : 6 mm Tip Dia X 2”Long Cable Length : 5 Meter Accuracy : Class A Range : 0 to 150 <sup>0</sup> C Qty : 5 Nos		
Temperature Sensor Refer IBD: 24-3-542	Make : Radix Type : Pt 100/ Duplex/ 3 Wire/ Fixed Size : 6 mm Tip Dia X 4” Long Accuracy : Class A Range : 0 to 250 <sup>0</sup> C Qty : 2 Nos		
Printer Refer IBD: 24-3-542	Make : Epson Model : LX 310 Function : To print online parameters.		



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## INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NON COMPLIES)	OBSERVED BY ENGINEERING SIGN/DATE
Strip Chart Recorder Refer IBD: 24-3-542	Make : Yokogawa No of Channels : Six No & type of inputs : 5T + 1P Temperature : 5 Nos, Pt100 Range : 0 to 200 <sup>0</sup> C Pressure : 1 No, 4 - 20 mA Range : -1 to 3 Bar		



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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**8.4.9 HANDLING ACCESSORIES :**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NON COMPLIES)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
Carriage Refer Carriage Diagram: 27-3-763	Type : 1/4 <sup>th</sup> MOC : SS316 Qty : 20 Nos Arrangement : shelves		

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

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

**Inference:**

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



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**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 P.O. and URS.
- Operating and service manual for High Pressure high vacuum steam sterilizer.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Process diagram.
- GA drawing
- Pneumatic diagram
- 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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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

%	:	Percent
&	:	And
°C	:	Degree Centigrade
AC	:	Alternate Current
BSP	:	British Standard for Pipe Threading
cGMP	:	Current Good Manufacturing Practice
Cm <sup>2</sup>	:	centimeter square
D	:	Depth
db	:	Decibel
DC	:	Direct current
FS	:	Full Scale
GA	:	General Arrangement
H	:	Height
SHS	:	Super Heated Water Spray Sterilizer
HMI	:	Human Machine Interface
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
I/P	:	Input
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



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O/P	:	Output
OD	:	Outer Diameter
P & ID	:	Piping and Instrumentation Diagram
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
Press.	:	Pressure
PVT.	:	Private
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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QUALITY ASSURANCE DEPARTMENT

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**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)			