



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

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

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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

**PROTOCOL CONTENT**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Project Requirements	6
6.0	Brief Equipment Description	6-12
7.0	Equipment Specification	13
8.0	Critical Variables to be Met	14
8.1	Process/ Product Parameter	15
8.2	Design Specification	15-28
8.3	Safety Feature & alarm	29
8.4	Process Detail	31
8.5	Utility Detail	32-34
8.6	Material of Concentration	45-46
8.7	Vendor Selection	46
9.0	Documents to be Attached	47
10.0	Review (Inclusive of Follow Up Action, If Any)	47
11.0	Any Changes Made Against the Formally Agreed Parameters	47
12.0	Recommendation	47
13.0	Abbreviations	48-49
14.0	Reviewed By	50



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**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY  
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 SUPER HEATED WATER SPRAY  
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 **Super Heated water Spray sterilizer (Make: Machinfabrik Industries Pvt. Ltd.)**.
- 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 SUPER HEATED WATER SPRAY  
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:

<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 Qualification Protocol cum Report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review 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 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><li>• Post Approval of Qualification Protocol after Execution.</li></ul>



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY  
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 the mutually agreed design, Change Control procedure shall be followed and documented and products are in accordance with cGMP principles.

**6.0 BRIEF EQUIPMENT 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. Machinfabrik 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



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

**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 bar 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.



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

**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).

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.





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

### **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.

### **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.



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

**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.

**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.



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

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 their 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.



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

- 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).
- 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 indication.



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

**7.0 EQUIPMENT SPECIFICATION:**

CUSTOMER	
PURCHASE ORDER NO. & DATE	
EQUIPMENT	SUPER HEATED WATER SPRAY STERILIZER
SIZE	1750 DIA X 4500 LG mm
CHAMBER VOLUME	10800 Liters
WORKING TEMPERATURE	UP TO 1340C
SERIAL NUMBER	
JOB NUMBER	



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

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 PROCESS / PRODUCT PARAMETERS:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
<p><b>Application:</b> Super Heated Water Spray Sterilizer is designed for the sterilization of Pharmaceutical Product, articles and supporting machine parts &amp; accessories which has to be used in production in three piece line.</p>	<p>All the loaded articles and supporting accessories should be sterile after performing the validated cycles.</p>	<p>Process Requirement</p>
<p><b>Working:</b> 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.</p>	<p>During Steam Sterilization, Steam distribution should be uniform in the chamber.</p>	<p>Process Requirement</p>



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

**8.2 DESIGN SPECIFICATION:**

**8.2.1 WORKING CONDITIONS & TEST PRESSURES**

	CHAMBER	H.E. OF SHWSS		AIR POCKET
		SHELL	TUBE	
<b>WORKING PRESSURE</b>	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)
<b>HYDRO TEST PRESSURE</b>	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.
<b>WORKING TEMPERATURE</b>	134 <sup>0</sup> C	142 <sup>0</sup> C	152 <sup>0</sup> C	60 <sup>0</sup> C
<b>VACUUM</b>	Full	N.A.	N.A.	Partial
<b>PNEUMATIC TEST</b>	N.A.	N.A.	N.A.	4.5 kg/cm <sup>2</sup> (g)

**8.2.2 SHELL DESIGN**

**8.2.2.1 CONSTRUCTIONAL DETAILS**

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



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

**8.2.2.2 SHELL INSULATION**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Material</b>	Resin Bonded Glass Wool	Design Requirements
<b>Thickness</b>	75 mm	Design Requirements
<b>Skin Temperature (Average)</b>	55 <sup>0</sup> C (Subjected to room temperature 23 ± 2 <sup>0</sup> C)	Design Requirements
<b>Cover Material</b>	SS304	Design Requirements
<b>Cover Thickness</b>	0.558 mm (24G)	Design Requirements

**8.2.2.3 SADDLE**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Material	Mild Steel	Design Requirements
Mounting	Pit Mounted	Design Requirements

**8.2.2.4 RAIL & BAFFLES**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Rail Pipe Material	SS316L	Design Requirements
Sprinkling Tray Material	SS316L	Design Requirements

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Piping Material of Chamber	SS316L	Design Requirements
Piping Material of Heat Exchanger	SS304	Design Requirements
Validation Port with Dummy Adaptor	MOC : SS316 No of Probes in Each Port : 8 Nos Qty : 2 Nos	Design Requirements





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

**8.2.3 .DOOR & DOOR COMPONENTS**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>DOOR</b>		
Type	Horizontal Sliding	Design Requirements
Quantity	Two	Design Requirements
Material	SS316L	Design Requirements
Finish	Ra ≤ 1.0 μm	Design Requirements
<b>Door Insulation</b>		
Material	Resin Bonded Glasswool	Design Requirements
Thickness	100 mm	Design Requirements
Outer Cover Material	SS304	Design Requirements
Outer Cover Material Thickness	1.25 mm (18G)	Design Requirements
<b>DOOR COMPONENTS</b>		
1. Door Component Material	SS304	Design Requirements
2. Door Extension Material	SS304	Design Requirements
3. 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.	Design Requirements
4. Solenoid Valves for Door Operating Cylinder (501, 502 & 503, 504) Refer Pneumatic Diagram: 25-3-1231	Make : Festo Model : JMFH - 5 ¼, Double coil Pneumatic Pressure : 1.5 – 8.0 Bar Coil supply : 1PH – 230V – 50Hz Qty : 2 Nos Function : To operate the door cylinders.	Design Requirements



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE										
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	Design Requirements										
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Part No.</th> <th style="text-align: center;">Design Requirements</th> <th style="text-align: center;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">507</td> <td style="text-align: center;">Design Requirements</td> <td rowspan="3" style="text-align: center;">Gasket Pressurization/ Retraction</td> </tr> <tr> <td style="text-align: center;">508</td> <td style="text-align: center;">Design Requirements</td> </tr> <tr> <td style="text-align: center;">511</td> <td style="text-align: center;">Design Requirements</td> </tr> </tbody> </table>		Part No.	Design Requirements	Function	507	Design Requirements	Gasket Pressurization/ Retraction	508	Design Requirements	511	Design Requirements
	Part No.		Design Requirements	Function								
	507		Design Requirements	Gasket Pressurization/ Retraction								
508	Design Requirements											
511	Design Requirements											
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.	Design Requirements										
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.	Design Requirements										
Compound Gauges (53, 54) Refer Pneumatic Diagram: 25-3-1231	Make : Forbes Marshall Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm <sup>2</sup> MOC : SS316 for Contact Part	Design Requirements										



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE									
	SS304 for Non Contact Part Accuracy : $\pm 1\%$ FS Qty : 2 Nos Connection : 3/8" BSP, Back Connection Function : Indication of gasket pressure.	Design Requirements									
. Filter Regulator Lubricator (5I) Refer Pneumatic Diagram: 25-3-1231	Make : Janatics/ Rotex Size : 1/4" BSP Range : 0.5 to 10 Bar Dial size : 2" Dial with 1/8" BSP Function : To filter, regulate & lubricate the incoming compressed air.	Design Requirements									
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	Design Requirements									
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Part No.</th> <th style="text-align: center;">Size</th> <th style="text-align: center;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">5J</td> <td style="text-align: center;">1/4" BSP</td> <td style="text-align: center;">Door Operation</td> </tr> <tr> <td style="text-align: center;">5K</td> <td style="text-align: center;">1/2" BSP</td> <td style="text-align: center;">Gasket Pressurization/ Retraction</td> </tr> </tbody> </table>		Part No.	Size	Function	5J	1/4" BSP	Door Operation	5K	1/2" BSP	Gasket Pressurization/ Retraction
Part No.	Size		Function								
5J	1/4" BSP		Door Operation								
5K	1/2" BSP	Gasket Pressurization/ Retraction									
Ejector Refer Pneumatic Diagram: 25-3-1231	Make : Unique Size : 1/2" X 3/4" Qty : 1 No Function : To retract door gasket before opening door.	Design Requirements									



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Ejector Refer Pneumatic Diagram: 25-3-1231	Make : Unique Size : ½” X ¾” Qty : 1 No Function : To retract door gasket before opening door.	Design Requirements
. 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.	Design Requirements
.Photocell Sensor	Make : P & F/ Optex Type : Single Path Model : M100/MV100- RT/76a/103/115 Qty : 2 Sets Function : Door obstruction safety.	Design Requirements

### 8.2.4 PANELLING

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Panelling	Only front paneling (As per layout)	Design Requirements
Material	SS304	Design Requirements
Finish	Ra ≤ 1.0 µm	Design Requirements
Mounting	Pit Mounted	Design Requirements



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

**8.2.5 WATER RECIRCULATION SYSTEM**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Transfer Tank Refer P & I Diagram: 22-3-1452	MOC : SS316L Capacity : 1200 Liters Function : To hold the process during leak testing.	Design Requirements
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.	Design Requirements
5.5.3. Motor for Transfer Pump	Make : Crompton/ Kirloskar/ LHP Type : Foot Mounted HP/RPM : 3 HP/ 2800 RPM Qty : 1 No	Design Requirements
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.	Design Requirements



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE																		
. 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>	Design Requirements																		
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	Design Requirements																		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Part No.</th> <th style="text-align: center;">Size</th> <th style="text-align: center;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">402</td> <td style="text-align: center;">1" BSP</td> <td>H/E Plant Steam in (Small)</td> </tr> <tr> <td style="text-align: center;">403</td> <td style="text-align: center;">1 ½" BSP</td> <td>H/E Cooling Water in (Small)</td> </tr> <tr> <td style="text-align: center;">405</td> <td style="text-align: center;">1 ½" BSP</td> <td>H/E Condensate Out</td> </tr> <tr> <td style="text-align: center;">406</td> <td style="text-align: center;">1" BSP</td> <td>H/E Exhaust</td> </tr> <tr> <td style="text-align: center;">412</td> <td style="text-align: center;">½" BSP</td> <td>H/E Vent Valve</td> </tr> </tbody> </table>		Part No.	Size	Function	402	1" BSP	H/E Plant Steam in (Small)	403	1 ½" BSP	H/E Cooling Water in (Small)	405	1 ½" BSP	H/E Condensate Out	406	1" BSP	H/E Exhaust	412	½" BSP	H/E Vent Valve
Part No.	Size		Function																	
402	1" BSP		H/E Plant Steam in (Small)																	
403	1 ½" BSP		H/E Cooling Water in (Small)																	
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	Design Requirements																		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Part No.</th> <th style="text-align: center;">Size</th> <th style="text-align: center;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">401</td> <td style="text-align: center;">3"</td> <td>H/E Plant Steam in (Big)</td> </tr> <tr> <td style="text-align: center;">404</td> <td style="text-align: center;">2 ½"</td> <td>H/E Cooling Water in (Big)</td> </tr> </tbody> </table>	Part No.	Size	Function	401	3"	H/E Plant Steam in (Big)	404	2 ½"	H/E Cooling Water in (Big)										
Part No.	Size	Function																		
401	3"	H/E Plant Steam in (Big)																		
404	2 ½"	H/E Cooling Water in (Big)																		



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
	409	3 ”	H/E Main Plant Steam in	Design Requirements
	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.			Design Requirements
. Manual Ball Valve (4403, 4408) Refer P & I Diagram: 22-3-1452	Make : President Type : 3 PC Design MOC : SS304 End Connection : Threaded			Design Requirements
	Part No.	Size	Function	
	4403	1 ½” BSP	H/E Cooling Water in (Small)	
	4408	¾” BSP	H/E Drain	



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

**8.2.6 ELECTRICAL CONTROL PANEL & POWER PANEL**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Type	Stand Alone	Design Requirements
Material	SS304	Design Requirements
Switch Gear	Contactor – Siemens Miniature Circuit Breaker – Siemens Over Load Relay – Siemens Indication Lamp – Siemens Terminal Block – Elmex/ Connectwell	Design Requirements

**8.2.6.1 CONTROL INDICATION ON UNLOADING SIDE**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</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>	Design Requirements
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>	Design Requirements





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

**8.2.6.2 CONTROL PANEL ON LOADING SIDE**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</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>	Design Requirements
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>	Design Requirements
MMI	The operator interface (E 1061) is fitted onto the Control Panel on the Loading side.	Design Requirements
Printer	The Printer is fitted onto the Control Panel on the Loading side.	Design Requirements
Strip Chart Recorder	The Strip Chart Recorder is fitted onto the Control Panel on the Loading side.	Design Requirements



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

**8.2.7 PROCESS CONTROL SYSTEM**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
Rotary Actuated Pneumatic Ball Valve (205, 206, 217, 219, 217A, 217B, 219A, 219B) Refer P & I Diagram: 22-3-1452	Make : Micro Pneumatics/ President  Type : Double Acting  MOC : SS316  End Connection : Threaded			Design Requirements
	Part No.	Design Requirements	Function	
	205	Design Requirements	Chamber process air in	
	206	Design Requirements	Chamber process air out	
	217	Design Requirements	Chamber Purified water in	
	219	Design Requirements	Chamber Drain	
	217A, 217B	Design Requirements	Transfer Tank Water into chamber	
	219A, 219B	Design Requirements	Chamber Water into Transfer Tank	



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
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.			Design Requirements
Manual Ball Valve (2219) Refer P & I Diagram: 22-3-1452	Make : President Type : 3 PC Design MOC : SS304 End Connection : Threaded			Design Requirements
	Part No.	Size	Function	Design Requirements
	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			Design Requirements
	Part No.	Size	Function	Design Requirements
	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			Design Requirements



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
	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			Design Requirements
	Part No.	Model	Function	
	2X	SMT-16- F82	Chamber Water Level Low	Design Requirements
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	Design Requirements
	25	1 ½” OD	Chamber process air in	



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE						
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.	Design Requirements						
Regulator (20B) Refer P & I Diagram: 22-3-1452	Make : Janatics/ Rotex Range : 0.5 To 10 Bar End Connection : Threaded	Design Requirements						
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Part No.</th> <th style="text-align: center;">Size</th> <th style="text-align: center;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">20B</td> <td style="text-align: center;">1" BSP</td> <td style="text-align: center;">To regulate the incoming process air</td> </tr> </tbody> </table>		Part No.	Size	Function	20B	1" BSP	To regulate the incoming process air
	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	Design Requirements						
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Part No.</th> <th style="text-align: center;">Design Requirements</th> <th style="text-align: center;">Function</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">20M</td> <td style="text-align: center;">Design Requirements</td> <td style="text-align: center;">To set pressure level of Chamber</td> </tr> </tbody> </table>		Part No.	Design Requirements	Function	20M	Design Requirements	To set pressure level of Chamber
	Part No.		Design Requirements	Function				
20M	Design Requirements	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	Design Requirements						



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
	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: 22-3-1452	Make : Orion Range : 0.5 – 10.0 bar End Connection : Threaded Qty : 2 Nos			Design Requirements
	Part No	Model	Function	
	3I	MG H10 KS 10	To set pressure level of compressed air	Design Requirements
	3K	MG H10 KS 10	To set pressure level of Process Air	



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

**8.2.8 VACUUM SYSTEM**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
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.			Design Requirements
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			Design Requirements
	Part No.	Size	Function	
	301	¾" 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			Design Requirements
	Part No.	Size	Function	
	202	2 ½"	Chamber Vacuum	



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA			REFERENCE
5.8.4. 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.			Design Requirements
Non Return Valve (2D, 2D1) Refer P & I Diagram: 22-3-1452	Make : Leader MOC : Brass End Connection : Threaded Qty : 2 Nos			Design Requirements
	Part No.	Size	Function	
	2D	2 ½” BSP	To prevent backflow from vacuum pump to chamber.	
	2D1	2 ½” BSP	To prevent backflow from vacuum pump to chamber.	





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

**8.2.9 INSTRUMENTATION:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
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.	Design Requirements
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 Free Relay Function : To add additional output to PLC.	Design Requirements
Communication Card Refer IBD: 24-3-542	Make : Mitsubishi Model : FX3U 232BD	Design Requirements
. 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.	Design Requirements



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
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.	Design Requirements
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.	Design Requirements
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.	Design Requirements
. 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	Design Requirements



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
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.	Design Requirements
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	Design Requirements
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	Design Requirements
Printer Refer IBD: 24-3-542	Make : Epson Model : LX 310 Function : To print online parameters.	Design Requirements
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	Design Requirements



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

**8.2.10 HANDLING ACCESSORIES**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Carriage Refer Carriage Diagram: 27-3-763	Type : 1/4 <sup>th</sup> MOC : SS316 Qty : 20 Nos Arrangement : shelves	Design Requirements

**8.3 SAFETY FEATURES & ALARMS**

**DOORS SAFETY:**

- No door opening when the process is on.
- Process will not start either in auto or manual if door is open.
- Door obstruction safety is provided, i.e. the door will retract to open if obstructed by hand or by any other object.

**DOOR /GASKET OPERATION:** Electro Pneumatic

**DOOR LOCKING SYSTEM:** Electro – Pneumatic through Process.

**ALARMS**

Alarms will be on if:

1. Temperature overshoots.
2. Sterilizer stops temperature.
3. Sterilizer resets temperature.
4. Circulating pump trips.
5. Chamber water level low.
6. Door precondition fail.
7. Air balancing fail.
8. Vacuum pump trip.
9. Transfer pump trips.
10. Plant steam pressure low.
11. Cooling water pressure low.
12. Process air pressure low.
13. Purified water pressure low.



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

14. Compressed air pressure low.

**8.4 PROCESS DETAILS**

The following process can be performed through **PLC**.

1. Sterilization – 1 to 7.
2. Ampoule Leak test – 8.

Programmed Parameters: Set through Man Machine Interface

Parameter Change: Password Protected.

(3 Level Password Protection for E 1061)

**MAINTENANCE MODE:**

In case of Emergency, The valves & pump in above-mentioned processes can be operated manually in maintenance mode with help soft key provided on MMI.



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

**8.4.1 PLC AND I/O CONFIGURATION**

**8.4.1.1 DIGITAL INPUT DETAILS**

S.No.	INPUT NAME	POSITION
1.	DOOR PRECONDITION	X0
2.	WATER LEVEL FLOAT SWITCH (HIGH)	X1
3.	WATER LEVEL FLOAT SWITCH (BOTTOM)	X2
4.	WATER LEVEL FLOAT SWITCH (MIDDLE)	X3
5.	CIRCULATING PUMP TRIPPED	X4
6.	PLANT STEAM PRESSURE	X5
7.	COOLING WATER PRESSURE	X6
8.	PROCESS AIR PRESSURE	X7
9.	PURIFIED WATER PRESSURE	X10
10.	EMERGENCY STOP	X11
11.	COMPRESSED AIR PRESSURE	X12
12.	VACUUM PUMP TRIPPED	X13
13.	TRANSFER PUMP TRIPPED	X14
14.	TRANSFER TANK FLOAT SWITCH (BOTTOM)	X15

**8.4.2 DIGITAL OUTPUT DETAILS:**

S.No.	OUTPUT NAME	POSITION
1.	PROCESS ON/END INDICATION	Y0
2.	H/E STEAM IN VALVE	Y1
3.	H/E STEAM INLET VALVE	Y2
4.	H/E STEAM INLET VALVE	Y3
5.	CIRCULATING PUMP	Y4
6.	COOLING WATER IN VALVE + H/E COOLING WATER OUT VALVE (403/407)	Y5
7.	COOLING WATER VALVE (404)	Y6
8.	H/E CONDENSATE VALVE (405)	Y7
9.	H/E EXHAUST VALVE (406)	Y10
10.	PROCESS AIR IN (205)	Y11



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

11.	PROCESS AIR OUT (206)	Y12
12.	ALARM	Y13
13.	VACUUM PUMP+VACUUM VALVE+ SOFTENED WATER TO VACUUM PUMP	Y14
14.	H/E VENT VALVE (412)	Y15
15.	PURIFIED WATER IN (217)	Y16
16.	CHAMBER DRAIN (219)	Y17
17.	PURIFIED WATER IN/ TRANSFER PUMP (217A, 217B)	Y20
18.	PURIFIED WATER OUT/ TRANSFER PUMP (219A, 219B)	Y21

### 8.4.3 ANALOG INPUTS

S.No.	INPUT NAME	RANGE	LEAST COUNT	POSITION
1.	H/E TEMPERATURE	0 TO 200°C	0.1°C	CH1 (FX3U 4AD ADP)
2.	BOTTLE TEMPERATURE-1	0 TO 200°C	0.1°C	CH2 (FX3U 4ADPTW ADP)
3.	BOTTLE TEMPERATURE-2	0 TO 200°C	0.1°C	CH3 (FX3U 4ADPTW ADP)
4.	BOTTLE TEMPERATURE-3	0 TO 200°C	0.1°C	CH4 (FX3U 4ADPTW ADP)
5.	BOTTLE TEMPERATURE-4	0 TO 200°C	0.1°C	CH5 (FX3U 4ADPTW ADP)
6.	BOTTLE TEMPERATURE-5	0 TO 200°C	0.1°C	CH6 (FX3U 4AD ADP)
7.	SUMP TEMPERATURE	0 TO 200°C	0.1°C	CH7 (FX3U 4AD ADP)
8.	CHAMBER PRESSURE	-1 TO 3 BAR	0.002 BAR	CH8 (FX3U 4AD ADP)



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

**8.4.4 SET PARAMETERS;**

PROCESS/PHASE	PARAMETER NAME (MMI)	UNIT
<b>STERILIZATION PROCESS - 1 TO 7</b>	INITIAL HE EXHAUST	XX MIN
	SET POINT 1	XXX.X DEG.C
	SET POINT 2	XXX.X DEG.C
	SET POINT 3	XXX.X DEG.C
	RATE 1	XXX.X DEG/MIN
	RATE 2	XXX.X DEG/MIN
	RATE 3	XXX.X DEG/MIN
	STER HOLD TEMP	XXX.X DEG.C
	STER HOLD TIME	XX MIN
	CONTROL BAND	XXX.X DEG.C
	OVER SHOOT TEMP	XXX.X DEG.C
	STER STOP TEMP	XXX.X DEG.C
	STER RESET TEMP	XXX.X DEG.C
	HE EXHAUST TIME	XX MIN
	SLOW COOLING END TEMP	XXX.X DEG.C
	COOLING END TEMPERATURE	XXX.X DEG.C
	H/E DRAIN TIME	XX MIN
H/E VENT DELAY TIME	XX MIN	
PROCESS END PRESSURE	X.XXX BAR	
<b>LEAK TEST - 8</b>	VACUUM	X.XXX BAR
	VACUUM HOLD TIME	XX MIN
	PRESSURE	X.XXX BAR
	NO OF POST PULSES	XX NOS
	PROCESS END PRESSURE	X.XXX BAR







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

**8.5.1 PRINTOUT FORMAT**

MFG BY : MACHINFABRIK INDUSTRIES PVT. LTD.  
CLIENT :  
MFG EQUIP. : SHWSS

PROCESS : STERILIZATION. PROCESS 1 TO 7

**SET PARAMETERS:**

INITIAL HE EXHAUST : XXX MIN  
SET POINT1 : XXX.X DEG.C  
SET POINT2 : XXX.X DEG.C  
SET POINT3 : XXX.X DEG.C  
RATE 1 : XX DEG.C / MIN  
RATE 2 : XX DEG.C / MIN  
RATE 3 : XX DEG.C / MIN  
STER HOLD TEMP : XXX.X DEG.C  
STER HOLD TIME : XXX MIN  
CONTROL BAND : XXX.X DEG.C  
OVERSHOOT TEMP : XXX.X DEG.C  
STER STOP TEMP : XXX.X DEG.C  
STER RESET TEMP : XXX.X DEG.C  
HE EXHAUST TIME : XX MIN  
SLOW COOLING END TEMP: XXX.X DEG.C  
COOLING END TEMP : XXX.X DEG.C  
H/E DRAIN TIME : XX MIN  
H/E VENT DELAY TIME : XX MIN  
PROCESS END PRESSURE: X.XXX BAR



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

MFG BY : MACHINFABRIK INDUSTRIES PVT. LTD.  
CLIENT :  
MFG EQUIP. : SHWSS

**BATCH DATA:**

STERILIZER NO : XXXXX  
BATCH NO : XXXXX  
OPERATOR CODE : XXXXX  
QTY : XXXXX  
PRINT INTERVAL : XXX SEC

DATE : DD/MM/YY  
TIME : HH: MM: SS

PROCESS : STERILIZATION PROCESS 1 TO 7

TIME	T1 DEG.C	T2 DEG.C	T3 DEG.C	T4 DEG.C	T5 DEG.C	P DEG.C.	STATUS DEG.C	BAR	
HH:MM:SS HEAT UP		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX	
HH:MM:SS STER HOLD		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX	
HH:MM:SS EXHAUST		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX	HE
HH:MM:SS COOLING		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX	
HH:MM:SS DRAIN		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX	HE
HH:MM:SS PROCESS END		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX	

DONE BY:  
DATE:

CHECKED BY:  
DATE:



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

MFG BY : MACHINFABRIK INDUSTRIES PVT. LTD.  
CLIENT :  
MFG EQUIP. : SHWSS

PROCESS : AMPOULE LEAK TEST

SET PARAMETERS:

VACUUM : X.XXX BAR  
VACUUM HOLD TIME : XXX MIN  
PRESSURE : X.XXX BAR  
NO OF POST PULSES : XX NOS  
PROCESS END PRESSURE: X.XXX BAR



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

MFG BY : MACHINFABRIK INDUSTRIES PVT. LTD.  
CLIENT :  
MFG EQUIP. : SHWSS

### BATCH DATA:

STERILIZER NO : XXXXX  
BATCH NO : XXXXX  
OPERATOR CODE : XXXXX  
QTY : XXXXX  
PRINT INTERVAL : XXX SEC

DATE : DD/MM/YY  
TIME : HH: MM: SS

PROCESS : AMPOULE LEAK TEST

TIME	T1 DEG.C	T2 DEG.C	T3 DEG.C	T4 DEG.C	T5 DEG.C	P DEG.C.	STATUS DEG.C	BAR
HH:MM:SS VACUUM		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX
HH:MM:SS VACUUM HOLD		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX
HH:MM:SS PRESSURE		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX
HH:MM:SS VACUUM BREAK		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX
HH:MM:SS PROCESS END		XXX.X	XXX.X	XXX.X	XXX.X	X.XXX	XXX.X	X.XXX

DONE BY:  
DATE:

CHECKED BY:  
DATE:



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

**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
25.	Float Switch	SS 316
26.	Pressure Switch	SS 304



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

S. No.	PARTS NAME	MATERIAL OF CONSTRUCTION
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

**8.7 VENDOR SELECTION:**

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Super-Heated Water Spay Sterilizer	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 P.O. and URS.

(2) Operating and service manual for Super-Heated Water Spay Sterilizer

**Checked By**  
**(Engineering)**

**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**

**Sign/Date:**.....

**Inference:**

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

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

**Sign/Date:** .....



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

**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):**

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**11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:**

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**12.0 RECOMMENDATION:**

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

**13.0 ABBREVIATIONS:**

AC	:	Alternate Current
BSP	:	British Standard for Pipe Threading
cGMP	:	Current Good Manufacturing Practice
Cm <sup>2</sup>	:	centimeter square
D	:	Depth
db	:	Decibel
DQ	:	Design Qualification
GA	:	General Arrangement
H	:	Height
HP	:	Horse Power
Hr	:	Hour
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
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
RTD	:	Resistance Temperature Detector
SHS	:	Super-Heated water Pray Sterilizer
SS	:	Stainless Steel



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

TC : Triclover  
Temp. : Temperature  
URS : User Requirement Specification  
V : Volt  
W : Width



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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

**14.0 REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (ENGINEERING)</b>			

DESIGNATION	NAME	SIGNATURE	DATE
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION )</b>			

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			