OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

EQUIPMENT ID. No.	
LOCATION	**Loading Area**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

PROTOCOL CONTENTS

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL 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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Super Heated Water Spray Sterilizer and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to qualification of Super Heated Water Spray Sterilizer **(Make:Machin febrik)** installed in the **Loading Area**.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity
- Successful completion of this Protocol Cum Report will verify that Super Heated Water Spray Sterilizer meet all acceptance criteria and ready for Performance Qualification.

OPERATIONAL 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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and compilation of the operational Qualification Protocol Cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report. • Post Approval of Operational Qualification Protocol after Execution.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Operational Qualification Protocol after Execution.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

5.0 EQUIPMENT DETAILS:

Equipment	Super Heated Water Spray Sterilizer
ID number	
Size	1750 DIA X 4500 LG mm
Chamber volume	10800 Liters
Working temperature	Upto 134^0C
Serial number	
Job number	
Loaction	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

OPERATIONAL 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 kg/cm^2 (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).

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.

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 $R_a \leq 1.0$ µm.

ii) The Chamber is designed to withstand a working pressure of 2.5 kg/cm^2 (g) and working temperature of 134^{o}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 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) Paneling on all loading & unloading sides are provided. The paneling is made up of Stainless Steel 304 Sheets having surface finish $R_a < 1\mu m$.

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 $R_a \leq 1.0\mu m$. 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

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 valuses.

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 in successfully completed then only you can open the Unloading side door.
- The door gasket will retracts 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

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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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
Executed and approved Design Qualification document				
Executed and approved Installation Qualification document				
Draft SOP for Operation & Cleaning of Super Heated Water Spray Sterilizer				
Draft SOP for Preventive Maintenance of Super Heated Water Spray Sterilizer				

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.3 OPEARATIONAL, AND FUNCTIONAL CHECKS:

OPERATIONAL CHECKS	ACCEPTANCE CRITERIA	OBSERVATION Complies / Non Complies	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Mains ON/OFF	All the control is activated, by keeping the control start switch in on position.		
Main Switch	When it is on switch on all control works		
Jacket Steam	Upon keeping this switch in ON position steam enters to the jacket		
Chamber Steam	Upon keeping this switch in ON position steam enters to the chamber		
Chamber Steam Exhaust	Upon keeping this switch in ON position steam, chamber exhaust valve to atmospheric opens.		
Jacket Steam Exhaust	Upon keeping this switch in ON position steam, jacket exhaust valve to atmospheric opens.		
Chamber air vent	Upon keeping this switch in ON position chamber vacuum brake & sterile air enters to the chamber.		
Chamber vacuum valve	Upon keeping this switch in ON position chamber inside air remove.		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.4 OPEARATIONAL, CHECKS FOR UTILITY:

Parameter	Plant steam for HE		Compressed Air		Cooling Water	
	Required	**Actual**	**Required**	**Actual**	**Required**	**Actual**
Pressure	3-6 Bar		6-7 kg/cm^2 (g)		1.2-1.4 kg/cm^2 (g)	
Line Size	3'' NB		½'' NB		3'' NB	
Quality	Dry & Saturated		Dry & Lubricated		Cooling water	
End Conn.	Flange		Flange		Flange	

Parameter	Process water (Purified)		Process Air		Softened Water	
	Required	**Actual**	**Required**	**Actual**	**Required**	**Actual**
Pressure	3-6 Bar		3-4 Bar		1.5 Bar	
Line Size	2'' NB		1'' NB		¾ '' NB	
Quality	Purified Water		Sterile & Oil Free		Cooling water	
End Conn.	Flange		Flange		Flange	

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.4.1 INSTRUMENT SETTINGS:

Parameter	For Door		Chamber		Heat Exchanger		Observed by (Engineering) (sign/date)
	Required	Actual	Required	Actual	Required	Actual	
Pressure Switch	5.5 kg/cm^2		……	……	……	…….	
Vacuum Switch	-0.5 kg/cm^2		-0.5 kg/cm^2		……	……	
Safety Valve	……	……	2.5 kg/cm^2		3.5 kg/cm^2		

8.4.2 FRL ASSEMBLY SETTING :

Parameter	Required	Observation	Observed by (Engineering) (sign/date)
Regulator for SLV	6.0 kg/cm2		
Regulator for Door	4.5 kg/cm2		
Regulator for Gasket	3.0 kg/cm2		

8.4.3 STRIP CHART RECORDER

Parameter	Required	Observation	Observed by (Engineering) (sign/date)
Temperature Range	0 – 200^{0}C		
Pressure Range	- 1 TO 3.0 BAR		

8.4.4 MOVEMENT:

Function	Required	Observation Complies /Non Complies	Observed by (Engineering) (sign/date)
Smooth Door Movement	Yes		
Smooth Carriage Movement	Yes		

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8.4.5 VERIFICATION OF SAFETY & INTERLOCKS

8.4.5.1 DOOR

SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Door obstruction	When unloading or loading door is moving upword, obstruct the door safety bar.	Door should move to downword.		
Opening of door during the running process operation	During running process operation, press unloading or loading door open push button.	Door should not open.		
Process does not start if door is open	Keep the unloading or loading door opened & start the process.	Process should not start.		
Process does not start if the door pre condition is not fulfilled.	Do not pressuries unloading or loading door gasket & start the process.	Process should not start.		
Both door cannot be open simultaneously	When unloading door is open, press loading door open push button	Loading door should not open		
After successful completion of sterilization cycle unloading side door should open	After successful completion of sterilization cycle, press loading door open push button	Loading door should not open		

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SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
After sterilization cycle is aborted, loading should be open	After cycle is aborted press, loading door open push button	Loading door should open		
After completion of unloading & unloading door acknowledge push button is pressed unloading door should not open & only loading side door should open	After completion of unloading & unloading door acknowledge push button is pressed. Press unloading door open push button & than press loading door open push button	Unloading door should not open & loading door should open		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.4.5.2 SAFETY VALVE:

SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Working of safety valves.	Increase chamber pressure more than working pressure of safety valve	Hot air From the Chamber will blow off		
	Increase jacket pressure more than working pressure of safety valve	Steam from heat Blow off		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.4.5.3 ALARM CHECKS

SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Over shooting of Temperature **(overshoot temp.)**	Set over shoot temperature Lesser then sterilization temperature & run the process in Auto Mode .	Alarm will generate when chamber temperature crosses over shoot temperature & Main Stem Inlet Valve will be Closed.		
Sterilization hold period counting stop **(ster. Stop temp.)**	During ster hold period after five minutes, stop chamber incoming steam supply. So that chamber temperature will fall down set Point	Alarm will be Generate & Counting will Stop .		
	Now, open Heat Exchanger steam supply	When the Heat Exchanger Temp. Attain Sterilization Temp. the Counting will Start Further From Where it Was Stopped & Alarm Will Stop		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Sterilization hold period counting reset	During the sterilization hold period, stop chamber incoming steam supply so that chamber temperature will fall down below ster. Reset temperature set point	Alarm will generate & counting will Stop		
	Now, open chamber steam supply	When the chamber attains sterilization temperature .the counting will start freshly (from zero) & alarm will stop.		
Circulation Pump	Dis Connect the Terminal Wire of Overload Relay of Circulating Pump	Alarm Indication will be ON and Process will Halt.		
Chamber Water Level Low	During Process Drop The Water Level Below the Middle Float Switch Level	Alarm will be Generate & Circulating Pump Will Trip & Process will Halt		
Door Precondition	If The Door Pre Condition Fail when Process Is ON	Alarm indication will be ON till it is Acknowledge		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Air Balancing Fail	During Sterilization Process High and Low Limit are Established art the Chamber Pressure at any Instant to Generate and Alarm in Case the Pressure Balancing Action is not Carried our Properly if Failure Last for More than Five Minute, Alarm will Be Generated	Alarm indication will be ON till it is Acknowledge and all Out Put will Shut off Except Circulating Pump.		
Vacuum Pump Trip	If the Vacuum Pump Trip When Process ON	Alarm indication will be ON till it is Acknowledge		
Transfer Pump Trip	If Transfer Pump Trip When Process ON	Alarm indication will be ON till it is Acknowledge		
Plant Steam Pressure Low	If The Transfer Pump Trip when Process ON	Alarm indication will be ON till it is Acknowledge		
Cooling Water Pressure Low	If the Pressure of Incoming Cooling water Below	Alarm indication will be ON till it is Acknowledge		
Process Air Pressure Low	If The Pressure Of Incoming Cooling Water Drop Below the Set Pressure	Alarm indication will be ON till it is Acknowledge		

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SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Purified Water Pressure Low	If The Pressure Of Incoming Water Drop Below the Set Pressure	Alarm indication will be ON & process will not condenser temperature sensor 3 in controlling		
Compressed Air Pressure Low	If The Pressure Of Incoming Compressed Air Drop Below the Set Pressure	Alarm indication will be ON & process will not condenser temperature sensor 4 in controlling		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.5 FEEDING OF PARAMETER SETTINGS FOR STERILIZATION PROCESS-1 to 7)

PARAMETER	PURPOSE	SET VALUE	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Add Water In	To maintain the water level	30 Sec.	
Initial H/E Exhaust	During the Steam in to H/E Remove the Condensate.	03 Min	
Set Point -1 (SP-1)	To Heat Load slowly	95.0°C	
Set Point -2 (SP-2)	To Heat Load Steadily	100.0°C	
Set Point -3 (SP-3)	To Close the Fast Heating Steam Inlet Valve & Open Control Steam Inlet Valve for Uniform Temperature	105.0°C	
Rate-1 (R-1)	To Increase Water Temperature at Uniform Rate	5.0°C	
Rate-2 (R-2)	To Increase Water Temperature at Uniform Rate	4.0°C	
Rate-3 (R-3)	To Increase Water Temperature at Uniform Rate	2.0°C	
Set Point -4 (SP-4)	Sterilization Temperature	108.0°C	
Sterilization Hold Period (T2)	To Soak The Temperature by Load	60 min	
Temperature Control Band	To Control Min. & Maximum Temperature During Sterilization Hold Period	0.2°C	
Overshoot Temperature	Sterilization Over Shoot Temperature	110.0°C	
Set Point -6 (SP-6)	Sterilization Time Counting Stop Temperature	107.5°C	
Set Point -7 (SP-7)	Sterilization Time Reset Temperature	107.0°C	

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

Heat Exchanger Exhaust Delay Time T3	To delay Exhaust From Heat Exchanger in Time T3	03 min	
Heat Exchanger Exhaust Time T4	To Exhaust From Heat Exchanger in Time T4	03 min	
Slow Cooling End Temperature	Opening of Fast Cooling valve	85.0°C	
Cooling End Temperature	To Cool the Circulating Water Temperature Rapidly	595.0°C	
HE Vent Delay Time	To Drain the Cooling Water by Gravity with the Help of Vent Valve	05 min	
Process End Pressure	Process End Pressure.	0.030 bar	
Note : Print Should be Attached			

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(Production)
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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SUPER HEATED WATER SPRAY STERILIZER

8.6 PARAMETER SETTINGS FOR AMPOULES LEAK TEST PROCESS-8

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
vacuum	To create vacuum in the Chamber	Bar		
Vacuum hold	To Stabilize the Vacuum in the Chamber	Min.		
Pre Pressure	To Break the Vacuum with Help of Filtered Air	Bar		
No of Post Pulse		Nos		
Process end pressure	To end the process & open the door.	Bar		
REFERANCE: Attach PLC Process Print Outs				

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

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

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9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Health Technical Memorandum 2010 Sterilization Part 3:Validation and verification
- Operational qualification from party

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of Draft SOPs.
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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:

°C	:	Degree centigrade
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
SHS	:	Super Heated Water Spray Sterilizer
ID.	:	Identification
LTD.	:	Limited
Ltrs	:	Liters
Min.	:	Minute
No.	:	Number
No.	:	Number
OQ	:	Operational Qualification
PVT.	:	Private
SOP	:	Standard operating procedure

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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)			