OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HPHV STEAM STERILIZER SIZE: 750 x 750 x 1200 mm

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

EQUIPMENT ID. No.	
LOCATION	**Unit Preparation Room (Three Piece Line)**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

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

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM 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 HPHV Steam 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 **HPHV Steam sterilizer (Make:Machinfebrik)** installed in the **Unit Preparation Room.**
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Autoclave Cum Bung Processor.
- Successful completion of this Protocol Cum Report will verify that HPHV Steam sterilizer meet all acceptance criteria and ready for Performance Qualification.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM 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.
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.

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

5.0 EQUIPMENT DETAILS:

Equipment Name	HPHV Steam Sterilizer
Equipment	…….
Manufacturer's Name	Machinfabrik
Supplier's Name	Machinfabrik
Location of Installation	Unit Preparation Room

6.0 EQUIPEMENT DESCRIPTION:

HPHV is a Jacketed Pressure Vessel. The Standard Steam Sterilization cycle is initiated by introducing Steam into the Jacket. This essentially aids in Preheating the Chamber and Effective Utilization of Heat Energy.

When a Particular Pressure inside the Jacket is achieved, Steam is introduced into the chamber. Air being heavier than Steam is displaced by Gravity Displacement Method which ensures Uniform Steam Distribution and Penetration. The equipment is also provided with Steam Traps with Air Vent to ensure Maximum Air Removal and Steam Condensate without allowing steam to pass through it.

As the Temperature of the Chamber increases, and reaches to the Sterilization Temperature, the control system in place controls this temperature for the Sterilization Time.

After the sterilization hold period is completed, steam from the chamber is exhausted to bring the chamber pressure to atmosphere.

The High pressure High Vacuum Steam Sterilization Process consists of following phases:-

- Vacuum steam pulsing
- Heat up
- Sterilization hold
- Vacuum drying
- Sterile air in

The Standard Steam Sterilization Process consists of following phases: -

- Heat up
- Sterilization hold
- Exhaust

A double door Steam Sterilizer is an industrial steam sterilizer especially designed for:

- Steam Sterilization of Garments.

- Steam Sterilization of Filtration Accessories.
- Steam Sterilization of Filling Machine Components, Manufacturing Accessories etc.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of HPHV Steam sterilizer.
- Draft SOP for Preventive Maintenance of HPHV Steam sterilizer.
- Electrical Circuits Diagram.
- Technical specification of equipment.

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 OQ 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 HIGH PRESSURE HIGH VACUUM STEAM 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.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Draft SOP for Operation & Cleaning of HPHV Steam sterilizer.				
4.	Draft SOP for Preventive Maintenance of HPHV Steam sterilizer				

Checked By
(Production)
Sign/Date: ……

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(Quality Assurance)
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Reviewed By
(Manager QA)
Sign/Date:…….

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM 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	Observed By Sign/Date

Checked By
(Production)
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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Sign/Date: ……

8.3 OPEARATIONAL, AND FUNCTIONAL CHECKS:

OPERATIONAL CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	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.		
Leakage	Should be less than 0.013 Bar		

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

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(Manager QA)
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8.4 Verification of Safety & Interlocks:

Safety	Method	Required	Observation	Observed By (Engineering) Sign/Date
Opening of door during auto or manual mode	When process is running in auto or manual mode operation press unloading or loading door open push button one by one	Door should not open		
Both the door can not open simultaneously	When Unloading door is open , press loading door open push button	Loading door should not open		
Unloading door opening	Unloading door will open only after successful completion of process.	Unloading door should not open		
Door is opened	Keep unloading door open & start the process. Do not pressurize unloading door gasket & start the process. Close the both side door & do not pressurize any one of them door.	Process should not start		
Door obstruction	When door is moving obstruct the door with hand or material.	Door should move back.		

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

loading door open after process is aborted	After sterilization cycle is aborted, loading should be open	After cycle is aborted press, loading door open push button		
Unloading door should not open &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	Unloading door should not open &loading door should open		

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

8.5 Alarm Checks

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Leak test fail	• During vacuum hold period, open filter air in valve by operating manual over ride facility on SLV for some time & then shut off. • The vacuum will be broken.	At the end of process alarm will generate		
Over shooting of Temperature (Overshoot temp.)	• Set over shoot temperature set point 2^0C more than sterilization temperature & run the process. Let temp. Rise above over shoot temp. Set point.	Alarm will generate & exhaust valve will open.		
Sterilization hold period counting stop (Ster. Stop	• During ster. hold period after five minutes, stop chamber incoming	Alarm will generate & counting will Stop when the		

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

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
temp.)	steam supply. So that chamber temperature will fall down to ster. stop temperature set point • Now, open chamber steam supply	chambers temp. Attain sterilization temp. The counting will start further from where it was stopped (i.e. After five minute) & alarm will stop		
Sterilization hold period counting reset (Ster. Reset temp.)	During the sterilization hold period, stop chamber incoming steam supply so that chamber temperature will fall down below set point	Alarm will generate & counting will reset to zero		
	Now, open chamber steam supply	When the chamber attains sterilization hold temperature the time counting will start freshly (from zero) & alarm will stop.		
Pure steam pressure low	If the pressure of incoming plant steam drop below the set pressure	Drop in steam pressure will be sensed by pressure. Alarm will generate & message will be		

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

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
		displayed on MMI.		
Soften water pressure low	During the process, put off cooling water utility supply.	Drop in water pressure will be sensed by pressure. Alarm will generate & message will be displayed on MMI.		
Process air pressure low	During the process, shut off process air utility supply or remove the input, physically from the PLC	Drop in air pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Compressed air pressure low.	During the process, increase setting if pressure switch mounted on compressed air inlet utility.	Alarm will be generated & message will be displayed on MMI		
W.F.I. pressure low	During the process, shut off W.F.I. utility supply or remove the input, physically from the PLC	Drop in water pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		

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

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Purified water pressure low	During the process, shut off purified water utility supply or remove the input, physically from the PLC	Drop in water pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Chamber pressure high	Allow the chamber pressure to rise more than chamber pressure high set point by opening the steam in valve manually	Alarm will be generated & exhaust valve will open & message will be displayed on MMI		
Too long time for pre vacuum	Set, TLT for pre vacuum set point less than actual required time (1 or 2 min.)	Alarm will be generated & message will displayed on MMI		
Too long time for post vacuum	Set, TLT for post vacuum set point less than actual required time (1 or 2 min.)	Alarm will be generated & message will displayed on MMI		
Too long time pre pressure	Set, TLT for pre pressure set point less than actual required time (1 or 2 min.)	Alarm indication will be ON till it is acknowledged.		
Too long time for post pressure	Set, TLT for post pressure set point less than actual required time (1 or 2 min.)	Alarm indication will be ON till it is acknowledged.		

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

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Vacuum pump trip	Trip the pump manually by the override provided on overload relay	Alarm will generate & message will be displayed on MMI.		
Too long time for heat up	Set, TLT for heat up set parameter lesser than actual required time (1 or 2 min.)	Alarm will be generated & message will be displayed on MMI		
Too long time for vacuum break	If the time required for breaking vacuum exceeds the set time in PLC	Alarm will be generated & message will be displayed on MMI till it acknowledge.		
Plant steam pressure low	If the pressure of incoming plant steam drop below the set pressure	Drop in steam pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Door precondition fail	During the process, put off compressed air utility supply.	Alarm will generate & message will be displayed on MMI		
Process end	When process is ends	Alarm indication will be ON till it is acknowledged.		
Chamber condensate temperature	If temperature sensor 1 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not		

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

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
sensor 1 fail		condenser temperature sensor 1 in controlling		
Chamber condensate temperature sensor 2 fail	If temperature sensor 2 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 2 in controlling		
Chamber condensate temperature sensor 3 fail	If temperature sensor 3 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 3 in controlling		
Chamber condensate temperature sensor 4 fail	If temperature sensor 4 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 4 in controlling		
Chamber condensate temperature sensor 5 fail	If temperature sensor 5 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not condenser temperature sensor 5 in controlling		

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

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Chamber pressure sensor (Transmitter) fail.	If the chamber pressure drops below -0.99 bar & goes above 2-9	Alarm indication will be ON & process will not halt (alarm to be rectified or process to be aborted manually in fail safe condition.		

Checked By
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Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date:

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

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

8.6 Safety Valve:

Safety	Method	Required	Observation	Observed By (Engineering) Sign/Date
Working of safety valves.	Increase chamber pressure by 15% of the working pressure.	Chamber steam will blow off through safety valve		
	Increase jacket pressure by 15% of the working pressure.	Jacket steam will blow off through safety valve		

Checked By **Verified By**

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

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(Manager QA)
Sign/Date: ……

8.7 Parameter Settings For Chamber Vacuum Leak Test (cold):

Parameter	Purpose	Set value	Observations	Observed By (Engineering) Sign/Date
Pre Vacuum	To create maximum vacuum	-0.700 bar.		
Delay before hold	To stabilize vacuum level after shutting off valve & pump	3 min.		
Vacuum hold time	To check the leakage during hold period	10 min.		
Acceptable Leakage	Maximum acceptable limit	0.013 bar.		
Process End Pressure	To end the process & open the door.	-0.030 bar.		

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

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Sign/Date: ……

8.8 Parameter Settings For Chamber Vacuum Leak Test (Hot):

Parameter	Purpose	Set value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 bar		
Pre pressure	To break the vacuum with steam	0.500 bar		
No. of pre pulses	To repeat the vacuum pressure pulses	3 nos		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 bar		

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

No. of pulses	To achieve effective heat distribution	5 nos		
Pre pressure down final	--	0.600 bar		
Small valve set point	--	120.0 °C		
Ster. Hold temp.	Sterilization	121.4°C g c		
Ster. Hold time	To hold the sterilization period as per the set time	10 min		
Temp. Control band	To control max & min level of temperature during sterilization period	0.2°C		
Overshoot temperature	To alarm the excess temperature in the chamber during sterilization hold period.	124.0 ° C		
Sterilization stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period.	120.9°C		
Sterilization reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5 °C		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 bar		
Post vacuum	To achieve set level of	-0.600 bar		

	vacuum			
Vacuum drying hold	--	5 min		
Delay before hold		3 min		
Vacuum hold time	To dry the load.	10 min		
Overshoot temperature	To alarm the excess temperature in the chamber during sterilization hold period.	124.0 °C		

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Sign/Date: ……

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(Quality Assurance
Sign/Date: ……

Inference:

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

8.9 Parameter Settings For warm up cycle

S.No.	Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
1.	Pre vacuum	To create vacuum for air removal	-0.600 bar		
2.	Warm up Temp	--	121.4 °C		
3.	Warm up Hold	--	10 min		
4.	Temp. Control band	To control max & min level of temperature during sterilization	0.2°C		

		period			
5.	Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.240 bar		
6.	Post vacuum	To achieve set level of vacuum	-0.600		
7.	Post vacuum hold time	To dry the load.	1min		
8.	Process end pressure	To end the process & allow to unload the material	-0.030 bar		

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(Production)
Sign/Date: ……

Verified By
(Quality Assurance
Sign/Date: ……

Inference:

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

8.10 Parameter Settings for Bowie Dick test:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 bar		
Pre pressure	To break the vacuum with steam	0.500 bar		
No. of pre pulses	To repeat the vacuum pressure pulses	3 Nos.		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre pressure up	For pressure pulses to improve heat distribution	0.700 bar		
Pre pressure down	For pressure pulses to improve heat distribution	0.300 bar		
Pre pressure down final	--	0.600 bar		
Small valve sp	--	120.0 °C		
Ster. Hold temp.	Sterilization	121.4°C		
Ster. Hold time	To hold the sterilization period as per the set time	17 min		
Temperature control band	To control max. & min. level of temperature during sterilization period	0.2 ° C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC		
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.9ºC		
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5ºC		
Process end pressure	To end the process & allow to unload the material	-0.030 Bar		

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Sign/Date: ……

Inference:

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

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Sign/Date: ……

8.11 Parameter Settings For Standard Process:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date

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

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	0.000 Bar		
Pre pressure	To break the vacuum with steam	0.000 Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	0 Nos.		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar		
No. of pulses	To achieve effective heat distribution	5 Nos.		
Pre pressure down final	--	0.600 Bar		
Small valve set point	--	120.0 ºC		
Ster. Hold temp.	Sterilization	121.4ºC		
Ster. Hold time	To hold the sterilization period as per the set time	30 Min		
Temp. Control band	To control max & min level of temperature during sterilization	0.2ºC		

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8.12 Parameter settings for HPHV Process:

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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	-0.600 Bar		
Pre pressure	To break the vacuum with steam	0.500 Bar		
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.		
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar		
No. of pulses	To achieve effective heat distribution	5 Nos.		
Pre pressure down final	--	0.600 Bar		
Small valve set point	--	120.0ºC		
Ster. Hold temp.	Sterilization	121.4ºC		
Ster. Hold time	To hold the sterilization period as per the set time	30 Min		
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC		
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar		
Post vacuum	To achieve set level of vacuum	-0.600 Bar		
Post vacuum	To dry the load.	5 Min		

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

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
hold time				
Post pressure	To break the vacuum by filtered air	-0.200 Bar		
No. Of post pulses	To achieve effective drying	2Nos		
Process end pressure	To end the process & allow to unload the material	-0.030 Bar		

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Sign/Date: ……

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

8.13 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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(Quality Assurance
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Sign/Date: ……

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

8.14 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the OFF button Pressed in, Try to cause movement of an Operating function.	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

Verified By
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Sign/Date: ……

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Sign/Date: ……

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

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

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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:

No.	:	Number
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
CQA	:	Corporate Quality Assurance
ID.	:	Identification
Ltrs	:	Liters
HPHV	:	High pressure high vacuum
IB	:	Injection block
No.	:	Number
SOP	:	Standard operating procedure
°C	:	Degree centigrade
Min.	:	Minute

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

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE

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

HEAD (QUALITY ASSURANCE)			