OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

HPHV STEAM STERILIZER

EQUIPMENT ID. No.	
LOCATION	**Unit Preparation Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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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: Machin febrik)** installed in the **Unit Preparation Room**.
- 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 HPHV Steam sterilizer meet all acceptance criteria and ready for Performance Qualification.

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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol Cum Report:

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.

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5.0 EQUIPMENT DETAILS:

Equipment	HPHV Steam Sterilizer
Id Number	……
Make	Machine Fabric
Sr. No.	…….
Chamber size	600 (w) x 600 (h) x 900 (d) mm
Chamber volume	324 liters
Working pressure	Upto 2.2 kg/cm^2 (g)
Working temperature	Upto 134^0c
Location of Installation	Unit Preparation area

6.0 EQUIPEMENT 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 High Pressure High Vacuum Sterilizer has been an unique Sterilization System offered by **M/s. Machinfabrik Industries Pvt. Ltd.,** as it can be efficiently used to perform two types of sterilization processes ; viz :-
    - **Standard Program**
    - **HPHV**

The identification for any leakage & penetration of steam can be tested by the following methods:

A) Chamber Leak Test (Cold)

B) Chamber Leak Test (Hot)

C) Warm up Cycle

D) Bowie Dick Test

- As the name suggests the above two processes achieve sterilization with the help of Steam.

  STANDARD STEAM STERILIZER:
  Standard Program is a jacketed pressure vessel. The Standard Program cycle is initiated by introducing steam into the jacket. This essentially aids in preheating the chamber and effective utilization of heat energy.

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The Standard Displacement Program process is made up of three phases viz:-

a. Heat Up

b. Sterilization Hold

c. Exhaust (Cooling)

When the pressure inside the jacket is reached up to a particular set pressure. Steam is introduced into the chamber & chamber Air pockets are removed through the chamber condensate line. This will ensure uniform steam distribution and penetration in the chamber. The equipment is provided with steam traps & air vent system in chamber condensate line to ensure maximum removal of air pockets and steam condensate along with some wet steam vapors.

As the chamber temperature reaches to set sterilization temperature, the control system then control's the chamber temperature till the end of sterilization time.

After the sterilization hold time is completed, steam from the chamber is exhausted to bring down the chamber pressure up to the set Process End Pressure (close to atmospheric pressure).

The sterile load is then unloaded in the sterile area.

HIGH PRESSURE HIGH VACUUM STEAM STERILIZATION:

The High Pressure High Vacuum Steam Sterilization cycle process is used to sterilize & dry the load.

The High Pressure High Vacuum Steam Sterilization cycle consists of following phases viz:-

a. Vacuum Steam Pulsing
b. Heat up
c. Sterilization Hold
d. Vacuum drying
e. Sterile Air In (Vacuum break)

This process is initiated by introducing steam into the jacket. This essentially aids in preheating the chamber and effective utilization of heat energy. In this process initially vacuum is created & then steam is introduced in the chamber up to the set value. These pulses are created 3 to 4 times to remove the air pockets. Almost 95% removal of air is ensured from chamber. The steam & vacuum pulsing not only ensures removal of air pockets and cold spots but also ensures uniform temperature distribution & penetration.

The vacuum is created with the help of water ring type vacuum pump.

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After completion of fixed no. of pulses, the chamber temperature reaches to set sterilization temperature. The control system then control's the chamber temperature till the end of sterilization time.

After the completion of sterilization time, vacuum up to a pre – determined level is created in the chamber. When this vacuum level is reached, the control system ensures that the vacuum is maintained for the specified time. The vacuum created at this stage ensures drying of the load inside the chamber.

After the completion of vacuum drying time, the –ve pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

The sterilized load is then unloaded from the chamber.

A. VACUUM LEAK TEST (COLD) :

- In this process initially vacuum is created up to the set level. Then it will hold as per the given delay hold time to settle down the vacuum in chamber, after that actual vacuum hold time will start (as per mention in HTM 2010 guideline) to know the chamber leakage. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

B. VACUUM LEAK TEST (HOT) :

1) In this process steam is introduced into the jacket, this preheats the chamber. After that vacuum is created & then steam is introduced in the chamber upto set value, these pulses are repeated 3 to 4 times to remove air pockets. In heat up, exhaust & steam pulses is repeated to for uniform temperature distribution & protection.
2) After completion of fixed no. of pulses the chamber temperature reaches to set sterilization temperature. The control system then control the chamber temperature tills the end of sterilization time.
3) After the sterilization chamber vacuum valve open to create vacuum & help in drying.
4) Then it will hold as per the given delay hold time to settle down the vacuum in chamber, after that actual vacuum hold time will start (as per mention in HTM 2010 guideline) to know the chamber leakage. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

C. WARM UP CYCLE :

1) In this process steam is introduced into the jacket, this preheats the chamber. After that

vacuum is created & then steam is introduced in the chamber upto set value.

2) After completion of vacuum pulses the chamber temperature reaches to set Warm temperature. The control system then control the chamber temperature tills the end of Warm hold time.

3) After the Warm hold chamber vacuum valve open to create vacuum & vacuum hold start. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

D. BOWIE DICK TEST :

1) In this process steam is introduced into the jacket, this preheats the chamber. after that vacuum is created & then steam is introduced in the chamber upto set value, these pulses are repeated 3 to 4 times to remove air pockets. In heat up exhaust & steam pulses is repeated to for uniform temperature distribution & protection.

2) After completion of fixed no. of pulses the chamber temperature reaches to set sterilization temperature. The control system then control the chamber temperature tills the end of sterilization time.

3) After the sterilization, Positive pressure in chamber is brought to atmospheric pressure by opening chamber exhaust valve.

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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.

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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 HPHV Steam sterilizer.				
Draft SOP for Preventive Maintenance of HPHV Steam sterilizer				

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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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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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8.4 OPEARATIONAL, CHECKS FOR UTILITY:

Parameter	Plant steam for Jacket		Soften Water for Vacuum System		Compressed Air		Pure steam for Chamber	
	Required	Actual	Required	Actual	Required	Actual	Required	Actual
Pressure	1.5 kg/cm^2 (g)		1.2 kg/cm^2 (g)		6-7 kg/cm^2 (g)		1.2-1.4 kg/cm^2 (g)	
Quality	Dry & Saturated		Soften Water, Less than 25^{0}C		Lubricated & Moisture free		Dry & Saturated	
Line Size	½" NB		½" NB		½" NB		¾" OD	
End Conn.	Triclover		Triclover		Triclover		Triclover	
Electricity	415V – 3PH – 50 Hz AC, 4 Wire Supply Control : 230 V – 1PH – 50 Hz Stabilize AC Supply							
Connected Load	Inductive Load : 3 HP							

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8.5 INSTRUMENT SETTINGS

8.5.1 AIR REGULATOR & FRL ASSEMBLY

COMPONENT	REQUIRED	OBSERVATION Complies / Non Complies	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Regulator of FRL Assembly for SLVS & Door Locking Cylinder	5.5 kg/cm^2		

8.5.2 SAFETY VALVES :

LOCATION	ACTUAL SET PRESSURE	OBSERVATION Complies / Non Complies	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Jacket	kg/cm^2		
Chamber	kg/cm^2		

8.5.3 STRIP CHART RECORDER

CHANNEL NOS	SET RANGE	OBSERVATION Complies / Non Complies	OBSERVED BY (ENGINEERING) (SIGN/DATE)
1 to 5^{th} Channel	$0 – 200^0C$		
6^{th} Channel	- 1 to 3.0 BAR		

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8.5.4 VERIFICATION OF SAFETY & INTERLOCKS

8.5.4.1 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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8.5.4.2 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	Chamber steam will blow off through safety valve		
	Increase jacket pressure more than working pressure of safety valve	Jacket steam will blow off through safety valve		
	Increase Steam Generator Pressure more then Working Pressure of Safety Valve	Water from Steam Generator will blow off		

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8.5.4.3 ALARM CHECKS

SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies/Non Complies)	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 when chamber temperature crosses over shoot temperature & exhaust valve will open.		
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 to ster stop temperature set point	When the chamber temp. Attain sterilization temp. The counting will start further from where it was stopped (i.e. After five minute) & alarm will stop		

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SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	Now, open chamber steam supply valve	Alarm will generate & counting 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 ster. Reset temperature set point	Alarm will generate & counting will reset to zero		
	Now, open chamber steam supply valve	When the chamber attains sterilization hold temperature the time counting will start freshly (from zero) & alarm will stop.		
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 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)
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 Acknowledge		
Too long time for heat up	Set, TLT for heat up set parameter lesser than actual required time (1 or 2 min.)	Alarm indication will be ON till it is Acknowledge		
Too long time for post vac	Set, TLT for post vacuum set point less than actual required time (1 or 2 min.)	Alarm indication will be ON till it is Acknowledge		
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 Acknowledge		
Too long time for vacuum break	If the time required for breaking vacuum exceeds the set time in PLC	Alarm indication will be ON till it is Acknowledge		
Vacuum pump trip.	Trip the pump manually by the override provided on overload relay	Alarm indication will be ON till it is Acknowledge		
Door precondition fail	During the process, put off compressed air utility supply.	Alarm indication will be ON till it is Acknowledge		
Process end	When the process is Ends	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)
Chamber condensate temperature sensor 1 fail	If temperature sensor 1 drops below 5^0C & goes above 175^0C	Alarm indication will be ON & process will not 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		

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SAFETY & INTER LOCK	METHOD	REQUIRED	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
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		
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.		

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8.6 PARAMETER SETTINGS FOR CHAMBER VACUUM LEAK TEST (COLD) (PROCESS-1)

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pre vacuum	To create maximum vacuum	Bar		
Delay before hold	To stabilize vacuum level after shutting off valve & pump	Min.		
Vacuum hold time	To check the leakage during hold period	Min.		
Acceptable leakage	Maximum acceptable limit	Bar		
Process end pressure	To end the process & open the door.	Bar		
REFERANCE: Attach PLC Process Print Outs				

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8.7 PARAMETER SETTINGS FOR VACUUM LEAK TEST (HOT) – PROCESS 2

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pre vacuum	To create vacuum for air removal	Bar		
Pre pressure	To break the vacuum with steam	Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	No.		
Pre Pressure up	For pressure pulses to improve heat distribution	Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	Bar		
No. of pulses	To achieve effective heat distribution	Nos		
Pre pressure down final	To improve heat distribution	Bar		
Small Valve set point	To switch over from big steam valve to small steam valve	^{0}C		
Ster. Hold temp.	Sterilization	^{0}C		
Ster. Hold time	To hold the sterilization period as per the set time	Min.		
Temp. Control band	To control max & min level of temperature during sterilization period	^{0}C		
Overshoot temperature	To alarm the excess temperature in the chamber during sterilization hold period.	^{0}C		
Sterilization stop	To stop sterilization hold	^{0}C		

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PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
temp.	time in case the chamber temperature falls below this value during sterilization period.			
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	Bar		
Post vacuum	To achieve set level of vacuum	Bar		
Vacuum drying hold	To remove the water content	Min.		
Delay before vacuum hold	To stablise the vacuum	Min		
Vacuum hold time	To check the leakage during hold period	min.		
Acceptance Leakage	Maximum acceptable limit.	Bar		
Process end pressure	To end the process.	Bar		
REFERANCE: Attach PLC Process Print Outs				

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8.8 PARAMETER SETTINGS FOR WARM UP CYCLE PROCESS – 3

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies / Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pre vacuum	To create vacuum for air removal	Bar		
Warm up Temp	To start the hold time	^{0}C		
Warm up Hold	To maintain the temp.	Min		
Post vacuum start pressure	To exhaust the steam from chamber & to start the vacuum pump	Bar		
Post vacuum	To achieve set level of vacuum	Bar		
Post vacuum hold time	To remove the water content	Min.		
Process end pressure	To end the process.	Bar		
REFERANCE : Attach PLC Process Print Outs				

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8.9 PARAMETER SETTINGS FOR BOWIE DICK TEST (PROCESS- 4)

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pre vacuum	To create vacuum for air removal	Bar		
Pre pressure	To break the vacuum with steam	Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	No.		
Pre Pressure up	For pressure pulses to improve heat distribution	Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	Bar		
No. of pulses	To achieve effective heat distribution	Nos		
Pre pressure down final	To improve heat distribution	Bar		
Small Valve set point	To switch over from big steam valve to small steam valve	^{0}C		
Ster. Hold temp.	Sterilization	^{0}C		
Ster. Hold time	To hold the sterilization period as per the set time	Sec.		
Temp. Control band	To control max & min level of temperature during sterilization period	^{0}C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	^{0}C		

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

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	^{0}C		
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period	^{0}C		
Process end delay time	--	Min		
Process end pressure	To end the process & allow to verify the results.	Bar		
REFERANCE: Attach PLC Process Print Outs				

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.10 PARAMETER SETTINGS FOR STANDARD PROCESS WITH SLOW & FAST EXHAUST – 5 & 6

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pre vacuum	To create vacuum for air removal	Bar		
Pre pressure	To break the vacuum with steam	Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	No.		
Pre Pressure up	For pressure pulses to improve heat distribution	Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	Bar		
No. of pulses	To achieve effective heat distribution	Nos		
Pre pressure down final	To improve heat distribution	Bar		
Small Valve set point	To switch over from big steam valve to small steam valve	^{0}C		
Ster. Hold temp.	Sterilization	^{0}C		
Ster. Hold time	To hold the sterilization period as per the set time	Sec.		
Temp. Control band	To control max & min level of temperature during sterilization period	^{0}C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	^{0}C		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	^{0}C		
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period	^{0}C		
Process end delay time	--	Min		
Process end pressure	To end the process & allow to verify the results.	Bar		
REFERANCE: Attach PLC Process Print Outs				

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.11 PARAMETER SETTINGS FOR H.P.H.V. PROCESS – 7,8,9,10 & 11

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pre vacuum	To create vacuum for air removal	Bar		
Pre pressure	To break the vacuum with steam	Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	No.		
Pre Pressure up	For pressure pulses to improve heat distribution	Bar		
Pre Pressure down	For pressure pulses to improve heat distribution	Bar		
No. of pulses	To achieve effective heat distribution	Nos		
Pre pressure down final	To improve heat distribution	Bar		
Small Valve set point	To switch over from big steam valve to small steam valve	^{0}C		
Ster. Hold temp.	Sterilization	^{0}C		
Ster. Hold time	To hold the sterilization period as per the set time	Min.		
Temp. Control band	To control max & min level of temperature during sterilization period	^{0}C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	^{0}C		
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls	^{0}C		

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

PARAMETER	PURPOSE	SET VALUE	OBSERVATION (Complies/Non Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	below this value during sterilization period.			
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	^{0}C		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	Bar		
Post vacuum	To achieve set level of vacuum	Bar		
Post vacuum hold time	To dry the load.	Min		
Post pressure	To break the vacuum by filtered air	Bar		
No. Of post pulses	To achieve effective drying	No		
Process end pressure	To end the process & allow to unload the material	Bar		
REFERENCE: Attach PLC Process Print Outs				

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.12 Emergency Operation Verification:

Item	Acceptance Criteria	OBSERVATION (Complies/Non Complies)	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
(Quality Assurance)
Sign/Date:……..

Inference:

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Reviewed By
(Manager QA)
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

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

16.0 ABBREVIATIONS:

°C	:	Degree centigrade
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HPHV	:	High pressure high vacuum
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
Ltrs	:	Liters
Min.	:	Minute
No.	:	Number
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard operating procedure

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

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)			