



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

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

|                               |                              |
|-------------------------------|------------------------------|
| <b>EQUIPMENT ID. No.</b>      |                              |
| <b>LOCATION</b>               | <b>Unit Preparation Room</b> |
| <b>DATE OF QUALIFICATION</b>  |                              |
| <b>SUPERSEDE PROTOCOL No.</b> | <b>NIL</b>                   |



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**1.0 PROTOCOL PRE – APPROVAL:**

**INITIATED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION           | NAME | SIGNATURE | DATE |
|-----------------------|------|-----------|------|
| HEAD<br>(PRODUCTION)  |      |           |      |
| HEAD<br>(ENGINEERING) |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
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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:Machinfabrik)** 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.



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**4.0 RESPONSIBILITY:**

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

| <b>DEPARTMENTS</b>       | <b>RESPONSIBILITIES</b>   |
|--------------------------|---|
| <b>Quality Assurance</b> | <ul style="list-style-type: none"><li>• Preparation, Review, Approval and compilation of the operational Qualification Protocol Cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li><li>• Monitoring of Operation Process.</li></ul>             |
| <b>Production</b>        | <ul style="list-style-type: none"><li>• Review of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report.</li><li>• Post Approval of Operational Qualification Protocol after Execution.</li></ul> |
| <b>Engineering</b>       | <ul style="list-style-type: none"><li>• Review of Operational Qualification.</li><li>• To co-ordinate and support Operational Qualification Activity.</li><li>• Calibration of Process Instruments.</li></ul>   |



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**5.0 EQUIPMENT DETAILS:**

|                                 |                       |
|---------------------------------|-----------------------|
| <b>Equipment Name</b>           | HPHV steam sterilizer |
| <b>Equipment</b>                |                       |
| <b>Manufacturer's Name</b>      |                       |
| <b>Supplier's Name</b>          |                       |
| <b>Location of Installation</b> | 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.



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- 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.



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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.

| 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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**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 |
|-----------------------------|---------------------------|----------------|--------|-----------------------|
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |
|                             |                           |                |        |                       |

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**8.3 OPEARATIONAL, AND FUNCTIONAL CHECKS:**

| <b>OPERATIONAL CHECKS</b>    | <b>ACCEPTANCE CRITERIA</b>  | <b>OBSERVATION</b> | <b>OBSERVED BY (ENGINEERING) (SIGN/DATE)</b> |
|------------------------------|---|--------------------|--|
| <b>Mains ON/OFF</b>          | All the control is activated, by keeping the control start switch in on position.                 |                    |  |
| <b>Main Switch</b>           | When it is on switch on all control works   |                    |  |
| <b>Jacket Steam</b>          | Upon keeping this switch in ON position steam enters to the jacket                                |                    |  |
| <b>Chamber Steam</b>         | Upon keeping this switch in ON position steam enters to the chamber                               |                    |  |
| <b>Chamber Steam Exhaust</b> | Upon keeping this switch in ON position steam, chamber exhaust valve to atmospheric opens.        |                    |  |
| <b>Jacket Steam Exhaust</b>  | Upon keeping this switch in ON position steam, jacket exhaust valve to atmospheric opens.         |                    |  |
| <b>Chamber air vent</b>      | Upon keeping this switch in ON position chamber vacuum brake & sterile air enters to the chamber. |                    |  |
| <b>Chamber vacuum valve</b>  | Upon keeping this switch in ON position chamber inside air remove.                                |                    |  |
| <b>Leakage</b>               | Should be less than 0.013 Bar   |                    |  |

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**8.4 Verification of Safety & Interlocks:**

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



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|  |   |   |  |  |
|--|---|---|--|--|
| <b>Unloading door should not open &amp; loading door should open</b> | 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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**8.5 Alarm Checks**

| Alarm  | Method  | Required   | Observation | Observed By<br>(Engineering)<br>Sign/Date |
|--|---|--|-------------|---|
| <b>Leak test fail</b>  | <ul style="list-style-type: none"> <li>During vacuum hold period, open filter air in valve by operating manual over ride facility on SLV for some time &amp; then shut off.</li> <li>The vacuum will be broken.</li> </ul>                                | At the end of process alarm will generate  |             |   |
| <b>Over shooting of Temperature</b><br>(Overshoot temp.)             | <ul style="list-style-type: none"> <li>Set over shoot temperature set point 2<sup>0</sup>C more than sterilization temperature &amp; run the process. Let temp. Rise above over shoot temp. Set point.</li> </ul>   | Alarm will generate & exhaust valve will open.   |             |   |
| <b>Sterilization hold period counting stop</b><br>(Ster. Stop temp.) | <ul style="list-style-type: none"> <li>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</li> <li>Now, open chamber steam supply</li> </ul> | Alarm will generate & counting will Stop when the chambers temp. Attain sterilization temp. The counting will start further from where it was stopped (i.e. After five minute) & alarm will stop |             |   |
| <b>Sterilization hold period counting reset</b>                      | During the sterilization hold period, stop chamber incoming steam supply so that chamber temperature  | Alarm will generate & counting will reset to zero  |             |   |



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| Alarm                               | Method   | Required  | Observation | Observed By<br>(Engineering)<br>Sign/Date |
|-------------------------------------|--|---|-------------|---|
| (Ster. Reset temp.)                 | will fall down below set point   |   |             |   |
|                                     | Now, open chamber steam supply   | When the chamber attains sterilization hold temperature the time counting will start freshly (from zero) & alarm will stop. |             |   |
| <b>Pure steam pressure low</b>      | 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 displayed on MMI.                  |             |   |
| <b>Softener water pressure low</b>  | 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.                  |             |   |
| <b>Process air pressure low</b>     | 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.                 |             |   |
| <b>Compressed air pressure low.</b> | During the process, increase setting if pressure switch mounted on compressed air inlet utility.     | Alarm will be generated & message will be displayed on MMI  |             |   |



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| Alarm  | Method  | Required  | Observation | Observed By<br>(Engineering)<br>Sign/Date |
|--|---|---|-------------|---|
| <b>W.F.I.<br/>pressure low</b>                 | 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. |             |   |
| <b>Purified<br/>water<br/>pressure low</b>     | 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. |             |   |
| <b>Chamber<br/>pressure high</b>               | 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                          |             |   |
| <b>Too long time<br/>for pre<br/>vacuum</b>    | 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   |             |   |
| <b>Too long time<br/>for post<br/>vacuum</b>   | 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   |             |   |
| <b>Too long time<br/>pre pressure</b>          | 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.  |             |   |
| <b>Too long time<br/>for post<br/>pressure</b> | 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.  |             |   |



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| Alarm   | Method   | Required  | Observation | Observed By (Engineering) Sign/Date |
|---|--|---|-------------|-------------------------------------|
| <b>Vacuum pump trip</b>                             | Trip the pump manually by the override provided on overload relay                    | Alarm will generate & message will be displayed on MMI.   |             |                                     |
| <b>Too long time for heat up</b>                    | 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  |             |                                     |
| <b>Too long time for vacuum break</b>               | 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.                               |             |                                     |
| <b>Plant steam pressure low</b>                     | 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. |             |                                     |
| <b>Door precondition fail</b>                       | During the process, put off compressed air utility supply.                           | Alarm will generate & message will be displayed on MMI  |             |                                     |
| <b>Process end</b>                                  | When process is ends   | Alarm indication will be ON till it is acknowledged.  |             |                                     |
| <b>Chamber condensate temperature sensor 1 fail</b> | If temperature sensor 1 drops below 5 <sup>0</sup> C & goes above 175 <sup>0</sup> C | Alarm indication will be ON & process will not condenser temperature sensor 1 in controlling                  |             |                                     |
| <b>Chamber condensate temperature sensor 2 fail</b> | If temperature sensor 2 drops below 5 <sup>0</sup> C & goes above 175 <sup>0</sup> C | Alarm indication will be ON & process will not condenser temperature sensor 2 in controlling                  |             |                                     |





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| Alarm  | Method   | Required   | Observation | Observed By (Engineering) Sign/Date |
|--|--|--|-------------|-------------------------------------|
| Chamber condensate temperature sensor 3 fail | If temperature sensor 3 drops below 5 <sup>0</sup> C & goes above 175 <sup>0</sup> C | 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 <sup>0</sup> C & goes above 175 <sup>0</sup> C | 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 <sup>0</sup> C & goes above 175 <sup>0</sup> C | 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 Safety Valve:

| Safety                           | Method  | Required   | Observation | Observed By<br>(Engineering)<br>Sign/Date |
|----------------------------------|---|--|-------------|---|
| <b>Working of safety valves.</b> | 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  |             |   |

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**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. |              |                                     |

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

| <b>Parameter</b>                | <b>Purpose</b>   | <b>Set value</b> | <b>Observations</b> | <b>Observed By<br/>(Engineering)<br/>Sign/Date</b> |
|---------------------------------|--|------------------|---------------------|--|
| <b>Pre vacuum</b>               | To create vacuum for air removal   | -0.600 bar       |                     |  |
| <b>Pre pressure</b>             | To break the vacuum with steam   | 0.500 bar        |                     |  |
| <b>No. of pre pulses</b>        | To repeat the vacuum pressure pulses   | 3 nos            |                     |  |
| <b>Pre Pressure up</b>          | For pressure pulses to improve heat distribution                                 | 0.700 bar        |                     |  |
| <b>Pre Pressure down</b>        | For pressure pulses to improve heat distribution                                 | 0.300 bar        |                     |  |
| <b>No. of pulses</b>            | To achieve effective heat distribution   | 5 nos            |                     |  |
| <b>Pre pressure down final</b>  | --   | 0.600 bar        |                     |  |
| <b>Small valve set point</b>    | --   | 120.0 °C         |                     |  |
| <b>Ster. Hold temp.</b>         | Sterilization  | 121.4°C g c      |                     |  |
| <b>Ster. Hold time</b>          | To hold the sterilization period as per the set time                             | 10 min           |                     |  |
| <b>Temp. Control band</b>       | To control max & min level of temperature during sterilization period            | 0.2°C            |                     |  |
| <b>Overshoot temperature</b>    | To alarm the excess temperature in the chamber during sterilization hold period. | 124.0 °C         |                     |  |
| <b>Sterilization stop temp.</b> | To stop sterilization hold time in case the chamber temperature falls            | 120.9°C          |                     |  |



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| Parameter                        | Purpose   | Set value  | Observations | Observed By (Engineering) Sign/Date |
|----------------------------------|---|------------|--------------|-------------------------------------|
|                                  | below this value during sterilization period.   |            |              |                                     |
| <b>Sterilization reset temp.</b> | To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period. | 120.5 °C   |              |                                     |
| <b>Post vacuum start press.</b>  | To exhaust the steam from chamber & to start the vacuum pump  | 0.200 bar  |              |                                     |
| <b>Post vacuum</b>               | To achieve set level of vacuum  | -0.600 bar |              |                                     |
| <b>Vacuum drying hold</b>        | --  | 5 min      |              |                                     |
| <b>Delay before hold</b>         |   | 3 min      |              |                                     |
| <b>Vacuum hold time</b>          | To dry the load.  | 10 min     |              |                                     |
| <b>Overshoot temperature</b>     | To alarm the excess temperature in the chamber during sterilization hold period.  | 124.0 °C   |              |                                     |

**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**

**8.9 Parameter Settings For warm up cycle**

| S.No. | Parameter                | Purpose   | Set Value  | Observations | Observed By<br>(Engineering)<br>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 period | 0.2°C      |              |   |
| 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.  | 1 min      |              |   |
| 8.    | Process end pressure     | To end the process & allow to unload the material                     | -0.030 bar |              |   |

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



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

**8.10 Parameter Settings for Bowie Dick test:**

| Parameter                | Purpose   | Set Value  | Observations | Observed By<br>(Engineering)<br>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  |              |   |
| 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.               | 124.0°C    |              |   |
| Ster. Stop temp.         | To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period      | 120.9°C    |              |   |
| Ster. Reset temp.        | To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period | 120.5°C    |              |   |



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| Parameter            | Purpose   | Set Value  | Observations | Observed By (Engineering) Sign/Date |
|----------------------|---|------------|--------------|-------------------------------------|
| Process end pressure | To end the process & allow to unload the material | -0.030 Bar |              |                                     |

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

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

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





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**8.11 Parameter Settings For Standard Process:**

| 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 °C  |              |                                     |
| Ster. Hold temp.        | Sterilization  | 121.4°C   |              |                                     |
| 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 | 0.2°C     |              |                                     |

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Sign/Date: .....

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Sign/Date: .....

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Sign/Date: .....



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

**8.12 Parameter settings for H.P.H.V. Process:**

| 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    | --  | 120.0°C    |              |                                     |
| Ster. Hold temp.         | Sterilization   | 121.4°C    |              |                                     |
| 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.               | 124.0°C    |              |                                     |
| Ster. 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 vacuum  | -0.600 Bar |              |                                     |



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| Parameter             | Purpose   | Set Value  | Observations | Observed By (Engineering) Sign/Date |
|-----------------------|---|------------|--------------|-------------------------------------|
| Post vacuum hold time | To dry the load.                                  | 5 Min      |              |                                     |
| 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: .....

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Sign/Date: .....

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Sign/Date: .....



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### 8.13 Power Failure Verification:

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

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

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

**Inference:**

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**(Manager QA)**  
**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<br>(Engineering)<br>(Sign/Date) |
|---|------------------------------------|-------------|---|
| ON/OFF Push button<br>• Press Stop Push Button<br>• 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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### 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:**

|      |   |                                      |
|------|---|--------------------------------------|
| 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            |
| 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<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION           | NAME | SIGNATURE | DATE |
|-----------------------|------|-----------|------|
| HEAD<br>(PRODUCTION)  |      |           |      |
| HEAD<br>(ENGINEERING) |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
| HEAD<br>(QUALITY ASSURANCE) |      |           |      |