# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

| | |
|---|---|
| **EQUIPMENT ID. No.** | |
| **LOCATION** | **UNIT PREPARATION ROOM** |
| **DATE OF QUALIFICATION** | |
| **SUPERSEDES REPORT No.** | **NIL** |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## REPORT CONTENTS

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 1.0 PROTOCOL 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) | | | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

## 3.0 SCOPE:

- The scope of this Report is limited for qualification of HPHV **Steam Sterilizer,** installed in **Unit Preparation Room.**
- This report provides all the relevant information of the Heat Penetration Study during Maximum Load with Decron Bag / Tyvek Bag to qualify the HPHV 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 Report:

| DEPARTMENTS | RESPONSIBILITIES |
|---|---|
| **Quality Assurance** | • Preparation, Review, Approval and Compilation of the Performance Re-qualification Review of Report.<br>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Re-qualification Activity.<br>• Monitoring of Performance Re-qualification.<br>• Post Approval of Performance Re-qualification Report After Execution. |
| **Production** | • Review of Performance Re-qualification Report.<br>• To co-ordinate and support Performance Re-qualification Activity.<br>• Post Approval of Performance Re-qualification Report After Execution. |
| **Quality Control** | • Analytical Support (Microbiological Testing/Analysis). |
| **Engineering** | • Reviewing of Re-qualification Report for correctness, completeness and technical excellence.<br>• Responsible for trouble shooting (if occurred during execution).<br>• Maintenance & preventive maintenance as per schedule.<br>• Post Approval of Performance Re-qualification Report After Execution. |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 5.0 EQUIPMENT DETAILS:

| | |
|---|---|
| **Equipment Name** | **HPHV Steam Sterilizer** |
| **Equipment** | |
| **Size** | 750 X 750 X 1200 mm |
| **C apacity** | 675 L. |
| **Manufacturer's Name** | |
| **Supplier's Name** | |
| **Location of Installation** | Unit Preparation Room |

## 6.0 PRE – RE-QUALIFICATION REQUIREMENTS:

### 6.1 Training Record of Validation Team:

- All the persons involved in the execution of qualification activity including the persons of outside agencies must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.
- Verify the training records and attached.

**Inference:**

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**Reviewed By:**
**(Manager QA)**
**(Sign & Date) ……....**

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

**6.2 Biological Indicator Detail :**

| BI Detail | Observation | Verified By (QA) Sign/date |
|---|---|---|
| **Name of Biological Indicator** | | |
| **Code Number** | | |
| **Lot Number** | | |
| **Spore Population** | | |
| **Z Value** | | |
| **D Valve** | | |
| **Manufacturing Date** | | |
| **Expiry Date** | | |

**Inference:**

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**Reviewed By**
**Manager QA)**
**(Sign & Date): ……...**

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.3 Chemical Indicator Detail :

| BI Detail | Observation | Verified By (QA) Sign/date |
|---|---|---|
| **Name of Chemical Indicator** | | |
| **Lot Number** | | |

**Inference:**

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**Reviewed By**
**Manager QA)**
**(Sign & Date): ……...**

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 7.0 TESTS AND CHECKS:

### 7.1 VACUUM LEAK TEST :

| VACUUM LEAK TEST DETAILS | |
|---|---|
| **Equipment Name** | |
| **Equipment Make** | |
| **Equipment Location** | |
| **Equipment ID No.** | |

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Started Date** | | |
| **Cycle Started Time** | | |
| **Pre Vacuum Level** | - 0.700 Bar | |
| **Vacuum Stabilize Delay** | 3Minute | |
| **Vacuum Hold Time** | 10 Minute | |
| **Process End Pressure** | 0.030 Bar | |
| **Acceptable Leakage** | 0.013 bar | |
| **Actual Leakage** | | |
| **Cycle Completed Date** | | |
| **Cycle Completed Time** | | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 7.2 BOWIE - DICK TEST:

| Bowie Dick Test Details | |
|---|---|
| **Equipment Name** | |
| **Equipment Make** | |
| **Equipment ID No.** | |
| **Equipment Location** | |

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date** | | |
| **Cycle Start Time** | | |
| Pre Vacuum | - 0.600 Bar | |
| Pre Pressure | 0.500 Bar | |
| No. of Pre Pulses | 03 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Pre pressure down final final | 0.600 bar | |
| No of positive pulses | 05 Nos. | |
| Sterilization Hold Temperature | 121.4 °C | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

| | | |
|---|---|---|
| Sterilization Hold Time | 11 Minute | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |
| Process End Pressure | 0.030 Bar | |
| **Cycle End Date** | | |
| **Cycle End Time** | | |
| **Observation of Color change in Bowie Dick Pack** | | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## Attach
## Bowie - Dick Test
## Indicator

**Observation:**
**Verified by:**

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.3 HEAT PENETRATION STUDY IN MFG ACCESSORIES LOAD-MAXIMUM LOAD (STANDARD PROCESS)

| | |
|---|---|
| Name of Cycle | Heat Penetration Study |
| Type of Cycle | Standard Process |

### 6.3.1 OBSERVATION OF CYCLE SET PARAMETER

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date** | | |
| **Cycle Start Time** | | |
| Pre Vacuum | 0.00 bar | |
| Pre Pressure | 0.00 bar | |
| No. of pre pulses | 0 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Nos. Of Positive Pulses | 5 Nos. | |
| Pre pressure down final | 0.600 bar | |
| Small valve SP | 120.0°C | |
| Sterilization Hold Temperature | 121.4 °C | |
| Sterilization Hold time | 30 Minute | |
| Temperature control band | 0.2 °C | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |
| Process End Pressure | 0.030 bar | |
| **Cycle End Time** | | |
| **Cycle End Date** | | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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

**Verified By**
**Quality Assurance)**
**Sign/Date**……

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.3.2 SUMMARY DETAIL OF STERILIZATION PROCESS

| S.No. | Critical variables | CYCLE |
|---|---|---|
| | | Internal |
| 1. | Date | |
| 2. | Set sterilization temperature | |
| 3. | Time process start | |
| 4. | Sterilization start Time | |
| 5. | Sterilization End Time | |
| 6. | Cycle end time | |
| 7. | Cold Point | |
| 8. | Sensor no | |
| 9. | Equilibrium Time | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.3.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

| Status of Chemical Indicator Strip | | | |
|---|---|---|---|
| **S.No.** | **Observation** | **S. No.** | **Observation** |
| **1** | | **7** | |
| **2** | | **9** | |
| **3** | | **9** | |
| **4** | | **10** | |
| **5** | | **11** | |
| **6** | | **12** | |

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.4 HEAT PENETRATION STUDY IN ORIENTATOR LOAD (STANDARD PROCESS)

| | |
|---|---|
| Name of Cycle | Heat Penetration Study |
| Type of Cycle | Standard Process |

### 6.4.1 OBSERVATION OF CYCLE SET PARAMETER

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date** | | |
| **Cycle Start Time** | | |
| Pre Vacuum | 0.00 bar | |
| Pre Pressure | 0.00 bar | |
| No. of pre pulses | 0 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Nos. Of Positive Pulses | 5 Nos. | |
| Pre pressure down final | 0.600 bar | |
| Small valve SP | 120.0°C | |
| Sterilization Hold Temperature | 121.4 °C | |
| Sterilization Hold time | 30 Minute | |
| Temperature control band | 0.2 °C | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |
| Process End Pressure | 0.030 bar | |
| **Cycle End Time** | | |
| **Cycle End Date** | | |

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

**Verified By**
**Quality Assurance)**
**Sign/Date**……

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.4.2 SUMMARY DETAIL OF STERILIZATION PROCESS

| S. No. | Critical variables | CYCLE |
|---|---|---|
| | | Internal |
| 1. | Date | |
| 2. | Set sterilization temperature | |
| 3. | Time process start | |
| 4. | Sterilization start Time | |
| 5. | Sterilization End Time | |
| 6. | Cycle end time | |
| 7. | Cold Point | |
| 8. | Sensor no | |
| 9. | Equilibrium Time | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.4.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

| Status of Chemical Indicator Strip | | | |
|---|---|---|---|
| **S.No.** | **Observation** | **S.No.** | **Observation** |
| **1** | | **7** | |
| **2** | | **9** | |
| **3** | | **9** | |
| **4** | | **10** | |
| **5** | | **11** | |
| **6** | | **12** | |

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.5 HEAT PENETRATION STUDY IN STERILE GARMENTS MAXIMUM LAOD IN HPHVPROCESS -1

| | |
|---|---|
| Name of Cycle | Heat Penetration Study |
| Type of Cycle | HPHV Process -1 |

### 6.5.1 OBSERVATION OF CYCLE SET PARAMETER

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date & Time** | | |
| Pre Vacuum | - 0.600 Bar | |
| Pre Pressure | 0.500 Bar | |
| No. of Pre pulses | 03 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Nos. Of Pre Pulses | 0 5 Nos. | |
| Pre pressure down final | 0.600 bar | |
| Small valve SP | 120.0°C | |
| Sterilization Hold Temperature | 121.4 °C | |
| Sterilization Hold time | 30 Minute | |
| Temperature Control band | 0.2 °C | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

| | | |
|---|---|---|
| Post vacuum start press. | 0.200 Bar | |
| Post vacuum | -0.600 Bar | |
| Post vacuum hold time | 5 Minute | |
| Post pressure | -0.200 bar | |
| No. of post pulses | 2 Nos. | |
| Process End Pressure | -0.030 Bar | |
| **Cycle End Time** | | |
| **Cycle End Date** | | |

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

**Verified By**
**Quality Assurance)**
**Sign/Date**……

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.5.2 SUMMARY DETAIL OF STERILIZATION PROCESS

| Sr. NO. | Critical variables | CYCLE |
|---|---|---|
| | | Internal |
| 01 | Date | |
| 02 | Set sterilization temperature | |
| 03 | Time process start | |
| 04 | Sterilization start Time | |
| 05 | Sterilization End Time | |
| 06 | Cycle end time | |
| 07 | Cold Point | |
| 08 | Sensor no | |
| 09 | Equilibrium Time | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.5.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

| Status of Chemical Indicator Strip | | | |
|---|---|---|---|
| **S. No.** | **Observation** | **S. No.** | **Observation** |
| **1** | | **7** | |
| **2** | | **9** | |
| **3** | | **9** | |
| **4** | | **10** | |
| **5** | | **11** | |
| **6** | | **12** | |

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.6 HEAT PENETRATION STUDY IN INNER GARMENTS MAXIMUM LAOD IN HPHVPROCESS -1

| | |
|---|---|
| Name of Cycle | Heat Penetration Study |
| Type of Cycle | HPHV Process -1 |

### 6.6.1 OBSERVATION OF CYCLE SET PARAMETER

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date & Time** | | |
| Pre Vacuum | - 0.600 Bar | |
| Pre Pressure | 0.500 Bar | |
| No. of Pre pulses | 03 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Nos. Of Pre Pulses | 0 5 Nos. | |
| Pre pressure down final | 0.600 bar | |
| Small valve SP | 120.0°C | |
| Sterilization Hold Temperature | 121.4 °C | |
| Sterilization Hold time | 30 Minute | |
| Temperature Control band | 0.2 °C | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

| | | |
|---|---|---|
| Post vacuum start press. | 0.200 Bar | |
| Post vacuum | -0.600 Bar | |
| Post vacuum hold time | 5 Minute | |
| Post pressure | -0.200 bar | |
| No. of post pulses | 2 Nos. | |
| Process End Pressure | -0.030 Bar | |
| **Cycle End Time** | | |
| **Cycle End Date** | | |

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

**Verified By**
**Quality Assurance)**
**Sign/Date**……

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.6.2 SUMMARY DETAIL OF STERILIZATION PROCESS

| Sr. NO. | Critical variables | CYCLE |
|---|---|---|
| | | Internal |
| 01 | Date | |
| 02 | Set sterilization temperature | |
| 03 | Time process start | |
| 04 | Sterilization start Time | |
| 05 | Sterilization End Time | |
| 06 | Cycle end time | |
| 07 | Cold Point | |
| 08 | Sensor no | |
| 09 | Equilibrium Time | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.6.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

| Status of Chemical Indicator Strip | | | |
|---|---|---|---|
| **S. No.** | **Observation** | **S. No.** | **Observation** |
| **1** | | **7** | |
| **2** | | **9** | |
| **3** | | **9** | |
| **4** | | **10** | |
| **5** | | **11** | |
| **6** | | **12** | |

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.7 HEAT PENETRATION STUDY IN MACHINE PARTS-MAXIMUM LOAD HPHVPROCESS -2

| | |
|---|---|
| Name of Cycle | Heat Penetration Study |
| Type of Cycle | HPHV Process -2 |

### 6.7.1 OBSERVATION OF CYCLE SET PARAMETER

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date & Time** | | |
| Pre Vacuum | - 0.600 Bar | |
| Pre Pressure | 0.500 Bar | |
| No. of Pre pulses | 03 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Nos. Of Pre Pulses | 0 5 Nos. | |
| Pre pressure down final | 0.600 bar | |
| Small valve SP | 120.0°C | |
| Sterilization Hold Temperature | 121.4 °C | |
| Sterilization Hold time | 30 Minute | |
| Temperature Control band | 0.2 °C | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

| | | |
|---|---|---|
| Post vacuum start press. | 0.200 Bar | |
| Post vacuum | -0.600 Bar | |
| Post vacuum hold time | 5 Minute | |
| Post pressure | -0.200 bar | |
| No. of post pulses | 2 Nos. | |
| Process End Pressure | -0.030 Bar | |
| **Cycle End Time** | | |
| **Cycle End Date** | | |

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

**Verified By**
**Quality Assurance)**
**Sign/Date**……

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.7.2 SUMMARY DETAIL OF STERILIZATION PROCESS

| Sr. NO. | Critical variables | CYCLE |
|---|---|---|
| | | Internal |
| 01 | Date | |
| 02 | Set sterilization temperature | |
| 03 | Time process start | |
| 04 | Sterilization start Time | |
| 05 | Sterilization End Time | |
| 06 | Cycle end time | |
| 07 | Cold Point | |
| 08 | Sensor no | |
| 09 | Equilibrium Time | |

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

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

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.7.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

| Status of Chemical Indicator Strip | | | |
|---|---|---|---|
| **S. No.** | **Observation** | **S. No.** | **Observation** |
| **1** | | **7** | |
| **2** | | **9** | |
| **3** | | **9** | |
| **4** | | **10** | |
| **5** | | **11** | |
| **6** | | **12** | |

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.8 HEAT PENETRATION STUDY IN FILTRATION ACCESSORIES-MAXIMUM LOAD HPHVPROCESS -2

| | |
|---|---|
| Name of Cycle | Heat Penetration Study |
| Type of Cycle | HPHV Process -2 |

### 6.8.1 OBSERVATION OF CYCLE SET PARAMETER

| Parameters | Set Value | Cycle Observed Value |
|---|---|---|
| **Cycle Start Date & Time** | | |
| Pre Vacuum | - 0.600 Bar | |
| Pre Pressure | 0.500 Bar | |
| No. of Pre pulses | 03 Nos. | |
| Pre pressure up | 0.700 bar | |
| Pre pressure down | 0.300 bar | |
| Nos. Of Pre Pulses | 0 5 Nos. | |
| Pre pressure down final | 0.600 bar | |
| Small valve SP | 120.0°C | |
| Sterilization Hold Temperature | 121.4 °C | |
| Sterilization Hold time | 30 Minute | |
| Temperature Control band | 0.2 °C | |
| Overshoot Temperature | 124.0 °C | |
| Sterilization Stop Temperature | 120.9 °C | |
| Sterilization Reset Temperature | 120.5 °C | |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

| | | |
|---|---|---|
| Post vacuum start press. | 0.200 Bar | |
| Post vacuum | -0.600 Bar | |
| Post vacuum hold time | 5 Minute | |
| Post pressure | -0.200 bar | |
| No. of post pulses | 2 Nos. | |
| Process End Pressure | -0.030 Bar | |
| **Cycle End Time** | | |
| **Cycle End Date** | | |

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

**Verified By**
**Quality Assurance)**
**Sign/Date**……

**Inference:**

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.8.2 SUMMARY DETAIL OF STERILIZATION PROCESS

| Sr. NO. | Critical variables | CYCLE |
|---|---|---|
| | | Internal |
| 01 | Date | |
| 02 | Set sterilization temperature | |
| 03 | Time process start | |
| 04 | Sterilization start Time | |
| 05 | Sterilization End Time | |
| 06 | Cycle end time | |
| 07 | Cold Point | |
| 08 | Sensor no | |
| 09 | Equilibrium Time | |

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

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

**Inference:**

……

……

……

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 6.8.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

| Status of Chemical Indicator Strip | | | |
|---|---|---|---|
| **S. No.** | **Observation** | **S. No.** | **Observation** |
| **1** | | **7** | |
| **2** | | **9** | |
| **3** | | **9** | |
| **4** | | **10** | |
| **5** | | **11** | |
| **6** | | **12** | |

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

| Tests or Checks | Executed (Yes/No) | Remarks |
|---|---|---|
| Vacuum Leak Test (Cold) | | |
| Bowie-Dick Test | | |
| Heat Penetration Study Standard Process (Manufacturing accessories)<br>a) Mfg accessories load-Minimum load<br>b) Mfg accessories load-Maximum load<br>c) Orientator load | | |
| Heat Penetration Study HPHV Process.- 01<br>a) Garment –minimum load<br>b)Garment –Maximum load<br>c)Inner garments –minimum load<br>d)Inner garments maximum load | | |
| Heat Penetration Study HPHV Process.- 02<br>a)Machine parts-Minimum load<br>b)Machine parts-Maximum load<br>c)Filtration accessories-Minimum load<br>d)Filtration accessories-Maximum load | | |

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

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

**Inference:**

……

……

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

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 9.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

## 10.0 NON COMPLIANCE:

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## 11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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## 12.0 CHANGE CONTROL, IF ANY:

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# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY 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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## 16.0 ABBREVIATIONS:

| | | |
|---|---|---|
| cGMP | : | Current Good Manufacturing Practices |
| DQ | : | Design Qualification |
| IQ | : | Installation Qualification |
| mm | : | Millimetre |
| No. | : | Number |
| OQ | : | Operational Qualification |
| PQ | : | Performance Qualification |
| SOP | : | Standard Operating Procedure |
| Sr. | : | Senior |
| SS | : | Stain less Steel |
| AFM | : | Ampoule Filling & Sealing Machine |
| WHO | : | World Health Organization |
| PVT | : | Private |
| LTD. | : | Limited |

# PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

## 17.0 REPORT POST APPROVAL:

**INITIATED 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) | | | |