



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

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

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



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

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**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	<ul style="list-style-type: none">• Preparation, Review, Approval and Compilation of the Performance Re-qualification Review of Report.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Re-qualification Activity.• Monitoring of Performance Re-qualification.• Post Approval of Performance Re-qualification Report After Execution.
Production	<ul style="list-style-type: none">• Review of Performance Re-qualification Report.• To co-ordinate and support Performance Re-qualification Activity.• Post Approval of Performance Re-qualification Report After Execution.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none">• Reviewing of Re-qualification Report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.• 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
Capacity	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 Value		
Manufacturing Date		
Expiry Date		

Inference:

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Reviewed By
Manager QA)
(Sign & Date):

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	
Acceptable Leakage	0.013 bar	
Process End Pressure	0.030 Bar	
Actual Leakage		
Cycle Completed Date		
Cycle Completed Time		

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
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(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	
No. of Positive Pulses	05 Nos.	
Pre pressure down final final	0.600 bar	
Small Valve SP	120.0 °C	
Sterilization Hold Temperature	121.4 °C	
Sterilization Hold Time	660 Sec.	
Temp. 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 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)
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PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

7.3 HEAT PENETRATION STUDY IN ORIENTATOR LOAD (STANDARD PROCESS)

Name of Cycle	Heat Penetration Study
Type of Cycle	Standard Process

7.3.1 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	05 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

7.3.2 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	

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

7.3.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

7.4 HEAT PENETRATION STUDY IN STERILE GARMENTS MAXIMUM LAOD IN HPHVPROCESS -1

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

7.4.1 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	05 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	
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	3 Nos.	
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

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(Production)
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(Quality Assurance)
Sign/Date:**.....

Inference:

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

7.4.2 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	

**Checked By
(Production)
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(Quality Assurance)
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PERFORMANCE QUALIFICATION REPORT FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

7.4.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

7.5 HEAT PENETRATION STUDY IN INNER GARMENTS MAXIMUM LAOD IN HPHV PROCESS -1

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

7.5.1 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	05 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	
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	3 Nos.	
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

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Sign/Date.....**

Inference:

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**Reviewed By
(Manager QA)
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7.5.2 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	

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

**Verified By
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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

7.5.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

**7.6 HEAT PENETRATION STUDY IN MACHINE PARTS-MAXIMUM LOAD
HPHVPROCESS -2**

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

7.6.1 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	05 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	
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		



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

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

Inference:

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

7.6.2 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	

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(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

7.6.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

**7.7 HEAT PENETRATION STUDY IN FILTRATION ACCESSORIES-I-MAXIMUM LOAD
HPHVPROCESS -2**

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

7.7.1 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	05 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	
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		



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

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(Production)**
Sign/Date:

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

Inference:

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

7.7.2 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	

**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**

7.7.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S.No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

**7.8 HEAT PENETRATION STUDY IN FILTRATION ACCESSORIES-II-MAXIMUM LOAD
HPHVPROCESS -2**

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

7.8.1 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	05 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	
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		



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

Parameters	Set Value	Cycle Observed Value
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:

7.8.2 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	

Checked By
(Production)
Sign/Date:

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

Inference:

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

7.8.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

**7.9 HEAT PENETRATION STUDY IN FILTRATION ACCESSORIES-III-MAXIMUM LOAD
HPHVPROCESS -2**

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

7.9.1 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	05 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	
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		



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:

7.9.2 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	

Checked By
(Production)
Sign/Date:

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

Inference:

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Reviewed By
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Sign/Date:



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

7.9.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

**7.10 HEAT PENETRATION STUDY IN PRESSURE VESSEL LOAD-MAXIMUM LOAD
HPHVPROCESS -2**

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

7.10.1 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	05 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	
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		



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:

.....
.....

Reviewed By
(Manager QA)
Sign/Date:

7.10.2 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	

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

7.10.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

7.11 HEAT PENETRATION STUDY IN MANUFACTURING ACCESSORY -MAXIMUM LOAD HPHVPROCESS -2

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

7.11.1 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	05 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	
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		



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:

.....
.....

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

7.11.2 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	

**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

7.11.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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



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

**7.12 HEAT PENETRATION STUDY IN MANUFACTURING FILTER-MAXIMUM LOAD
HPHVPROCESS -2**

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

7.12.1 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	05 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	
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		



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:

.....
.....

Reviewed By
(Manager QA)
Sign/Date:

7.12.2 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	

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

7.12.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip			
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6			

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		
Bowie-Dick Test		
Orientator load		
Sterile Garment –Maximum load		
Inner Garment –Maximum load		
Machine Parts –Maximum load		
Filtration Accessory-I-Maximum load		
Filtration Accessory-II-Maximum load		
Filtration Accessory-III-Maximum load		
Pressure Vessel Load-Maximum load		
Manufacturing accessories load-Maximum load		
Manufacturing Filter Housing Load Maximum load		

Checked By
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Sign/Date:

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(Quality Assurance)
Sign/Date:.....

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



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

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)			