

PROTOCOL No.:

# PERFORMANCE QUALIFICATION REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

EQUIPMENT ID. No.	
LOCATION	UNIT PREPARATION ROOM
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



PROTOCOL No.:

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**INITIATED BY:** 

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### **REVIEWED BY:**

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

#### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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#### 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 performance qualification activity, In-process observations and analytical data of testing of collected samples.



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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 Report:

DEPARTMENTS		RESPONSIBILITIES				
<b>Quality Assurance</b>	•	Preparation, Authorization, Approval and Compilation of the				
		Performance Qualification Review of Report.				
	•	Co-ordination with Quality Control, Production and Engineering to				
		carryout Performance Qualification Activity.				
	•	Monitoring of Performance Qualification.				
Production	•	Review of Report.				
	•	To co-ordinate and support Performance Qualification Activity.				
<b>Quality Control</b>	•	Review of Report.				
	•	Analytical Support (Microbiological Testing/Analysis).				
Engineering	•	Reviewing of qualification Report for correctness, completeness and				
		technical excellence.				
	•	Responsible for trouble shooting (if occurred during execution).				
	•	Maintenance & preventive maintenance as per schedule.				
<b>External Qualification</b>	•	Performance of qualification activity as per protocol				
Agency ( if Applicable)		refrontibilities of qualification activity as per protocor				



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#### **5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	HPHV Steam sterilizer
Equipment	
Size	750 X 750X 1200
Manufacturer's Name	
Supplier's Name	
<b>Location of Installation</b>	Unit Preparation Room



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#### 6.0 PRE – QUALIFICATION REQUIREMENTS:

Record the observations for documents in the below mentioned table.

S. No.	<b>Document Name</b>	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	<b>Executed and approved</b>				
	<b>Design Qualification</b>				
	document				
2.	<b>Executed and approved</b>				
	<b>Installation Qualification</b>				
	document				
3.	Executed and approved				
	<b>Operational Qualification</b>				
	document				
4.	PQ Protocol approved				
5.	SOP for Operation &				
	Cleaning of HPHV Steam				
	sterilizer				
6.	<b>SOP</b> for Preventive				
	Maintenance of HPHV				
	Steam sterilizer		_		
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Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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7.0 TESTS AN	ND CHECKS:
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#### 7.1 VACUUM LEAK TEST:

	VACUU	M LEAK TEST DET	CAILS	
<b>Equipment Name</b>				
<b>Equipment Make</b>				
Equipment ID No.				
Date				
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
Date				
Pre Vacuum	- 0.700 Bar			
Delay before Hold	3 Minute			
Vacuum Hold time	10 Minute			
Acceptable Leakage	0.013 Bar			
Actual Leakage				
Process End Pressure	- 0.040 Bar			
Cycle Started				
<b>Cycle Completed</b>				
Checked By			Verified B	<b>y</b>
(Production)			(Quality A	
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#### 7.2 WARM UP CYCLE:

7.2 WARM OF CICLE.						
	WARM UP (	CYCLE TEST DE	TAILS			
<b>Equipment Name</b>						
<b>Equipment Make</b>						
<b>Equipment ID No.</b>						
Date						
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3		
Date						
Pre Vacuum	- 0.500 Bar					
Warm up hold temperature	121.4°C					
Warm up hold	10 min.					
Temperature control band	0.2 °C					
Post vacuum start pressure	0.200 bar					
Post vacuum	-0.400					
Post vacuum hold time	1 min.					
Process End Pressure	- 0.040 Bar					
Cycle Started						
Cycle Completed						
Checked By			Verified B	v		
(Production)			(Quality Assurance)			
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#### 7.3 VACUUM LEAK TEST IN HOTCONDITION:

VACUUM LEAK TEST IN HOTCONDITION				
<b>Equipment Name</b>				
<b>Equipment Make</b>				
Equipment ID No.				
Date				
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
Date				
Cycle started at				
Pre vacuum	-0.600 bar			
Pre pressure	0.500 bar			
No. of pre pulses	3 nos			
Pre Pressure up	0.700 bar			
Pre Pressure down	0.300 bar			
No. of pulses	5 nos			
Pre pressure down final	0.600 bar			
Small valve set point	120.0 °C			
Ster. Hold temp.	121.4°C			
Ster. Hold time	10 min			
Temp. Control band	0.2°C			
Overshoot temperature	124.0 ° C			
Sterilization stop temp.	120.9°C			
Sterilization reset temp.	120.5 °C			
Post vacuum start press.	0.200 bar			
Post vacuum	-0.500 bar			
Vacuum drying hold	5 min			
	•	•	•	•



**Delay before hold** 

Vacuum hold time

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#### HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

3 min

10 min

Acceptable leakage	0.013 bar		
<b>Process end pressure</b>	-0.030 bar		
Cycle Completed			
Checked By		Verified B	•
(Production)		(Quality A	
Sign/Date:		Sign/Date	
Inference:			
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		Reviewed	Ву
		(Manager	
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#### 7.4 BOWIE - DICK TEST:

	Bowie Dick Test Details
<b>Equipment Name</b>	
Equipment Make	
Equipment ID No.	

#### **OBSERVATION OF CYCLE PARAMETER**

Parameters	Set Value	Observed Value				
1 arameters	Set value	Cycle - 1	Cycle - 3			
Cycle Start Date & Time		VB				
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	0.600 bar					
Small valve SP	120.0 °C					
Sterilization Hold Temperature	121.4 °C					
Sterilization Hold Time	660 sec.					
Control band	0.2 °C					
Overshoot Temperature	124.0 °C					



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Parameters	Set Value	Observed Value				
1 drumeters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Sterilization Stop Temperature	120.9°C					
Sterilization Reset Temperature	120.5 °C					
Process End Pressure	0.040 Bar					
Cycle End Date & Time						
Observation of Color change in Bowie						
Dick Pack						

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



**Observation:** 

#### PERFORMANCE QUALIFICATION REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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Attach	
Bowie - Dick Test	t
Indicator	

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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Attach
<b>Bowie - Dick Test</b>
Indicator

Observation:	
Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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 	Verified By (Quality Assurance) Sign/Date



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#### 7.5 EMPTY CHAMBER HEAT DISTRIBUTION STUDY FOR HPHV PROCESS -1

<b>Test Instrument Name</b>			
Make			
Sensors Type & Quantity			
Calibration done Date			
Calibration due Date			
Type of cycle	High pressure high vacuum	cvcle	
	angi prossure ingli vucuum		

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<b>Equipment Name</b>			Equipment ID	
<b>Equipment Make</b>			Equipment Location	

#### **OBSERVATION OF CYCLE PARAMETER**

Parameters	Set Value	Observed Value			
Parameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3	
Cycle Start Date					
Cycle Start Time					
Pre Vacuum	- 0.600 Bar				
Pre Pressure	0.500 Bar				
No. of Pre pulses	3 Nos.				
Pre Pressure up	0.700 Bar				
Pre Pressure down	0.300 Bar				
No. of pulses	5 Nos.				
Pre pressure down final	0.600 Bar				
Small valve set point	120.0 °C				
Sterilization Hold Temperature	121.4 °C				



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Parameters	Set Value	Observed Value			
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3	
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	-0.500 Bar				
Post vacuum hold time	5 Minute				
Post pressure	-0.100 Bar				
No. of post pulses	3 Nos.				
Process End Pressure	-0.040 Bar				
Cycle End Date & Time					
Cycle End Time					

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date		-
Inference:			
		Reviewed By (Manager Q. Sign/Date:	



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#### SUMMARY DETAIL OF STERILIZATION PROCESS

S No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1.	Date			
2.	Sterilization Set temperature			
3.	Time Process start			
4.	Sterilization start time			
5.	Sterilization end time			
6.	Cycle end time			
7.	Performed By			
8.	Checked By			

#### SUMMARY DETAIL OF STERILIZATION PROCESS (WITH EXTERNAL SENSORS)

S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1.	Date			
2.	Sterilization Set temperature			
3.	Time Process start			
4.	Sterilization start time			
5.	Sterilization end time			
6.	Cycle end time			
7.	Performed By			
8.	Checked By			

(Production) Sign/Date:	(Quality Assurance) Sign/Date
Inference:	
	Reviewed By (Manager QA) Sign/Date:



**Equipment Make** 

#### PERFORMANCE QUALIFICATION REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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#### 7.6 EMPTY CHAMBER HEAT DISTRIBUTION STUDY FOR HPHV PROCESS -11

Test Instrument Name			
Make			
Sensors Type & Quantity			
Calibration done Date			
Calibration due Date			
Type of cycle	High pressure high vacuum cycle		
<b>Equipment Name</b>		<b>Equipment ID</b>	

#### **OBSERVATION OF CYCLE PARAMETER**

**Equipment Location** 

Parameters	Set Value	Observed Value			
1 arameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3	
Cycle Start Date					
Cycle Start Time					
Pre Vacuum	- 0.600 Bar				
Pre Pressure	0.500 Bar				
No. of Pre pulses	3 Nos.				
Pre Pressure up	0.700 Bar				
Pre Pressure down	0.300 Bar				
No. of pulses	5 Nos.				
Pre pressure down final	0.600 Bar				
Small valve set point	120.0 °C				
Sterilization Hold Temperature	121.4 °C				



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Parameters Set Value		Observed Value			
Tarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3	
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	-0.500 Bar				
Post vacuum hold time	5 Minute				
Post pressure	-0.100 Bar				
No. of post pulses	2 Nos.				
Process End Pressure	-0.040 Bar				
Cycle End Date & Time					
Cycle End Time					

Cycle End Time		
Checked By (Production) Sign/Date:	Verified By (Quality Ass Sign/Date	urance)
Inference:		
	Reviewed By (Manager Qa Sign/Date:	



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SU	MMARY DETAIL OF STERIL	IZATION PROC	ESS	
S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1	Date			
2	Sterilization Set temperature			
3	Time Process start			
4	Sterilization start time			
5	Sterilization end time			
6	Cycle end time			
7	Performed By			
8	Checked By			
SU	MMARY DETAIL OF STERIL	ZATION PROC	ESS (WITH EXTER	NAL SENSORS)
S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
S.No.	Critical variables  Date	Cycle -1	Cycle -2	Cycle -3
		Cycle -1	Cycle -2	Cycle -3
1	Date	Cycle -1	Cycle -2	Cycle -3
1 2	Date Sterilization Set temperature	Cycle -1	Cycle -2	Cycle -3
1 2 3	Date Sterilization Set temperature Time Process start	Cycle -1	Cycle -2	Cycle -3
1 2 3 4	Date Sterilization Set temperature Time Process start Sterilization start time	Cycle -1	Cycle -2	Cycle -3
1 2 3 4 5	Date Sterilization Set temperature Time Process start Sterilization start time Sterilization end time	Cycle -1	Cycle -2	Cycle -3
1 2 3 4 5	Date Sterilization Set temperature Time Process start Sterilization start time Sterilization end time Cycle end time	Cycle -1	Cycle -2	Cycle -3

Inference:

Reviewed By (Manager QA) Sign/Date:



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#### 7.7 EMPTY CHAMBER HEAT DISTRIBUTION STUDY FOR STANDARD PROCESS:

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Type of cycle	Standard cycle		
<b>Equipment Name</b>		<b>Equipment ID</b>	
<b>Equipment Make</b>		<b>Equipment Location</b>	

#### OBSERVATION OF CYCLE PARAMETER

Do wowe stores Cot Volus		Observed Value			
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3	
Cycle Start Date & 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				
No. of pulses	5 Nos.				
Pre pressure down final	0.600 Bar				
Small valve SP	120 °C				
Sterilization Hold Temperature	121.4°C				
Sterilization Hold time	30 Minute				
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	0.040 Bar				
Cycle End Date	Cycle End Date				
Cycle End Time					



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Sr No.	Critical variables	Cycle -1	Cycle -2	Cycle -3		
01	Date					
02	Sterilization Set temperature					
03	Time Process start					
04	Sterilization start time					
05	Sterilization end time					
06	Cycle end time					
07	Performed By					
08	Checked By					
SU	  MMARY DETAIL OF STERIL	IZATION PROC	CESS (WITH EXTER	NAL SENSORS)		
Sr No.	Critical variables	Cycle -1	Cycle -2	Cycle -3		
01	Date		oşete 2	Syste 5		
02	Sterilization Set temperature					
03	Time Process start					
04	Sterilization start time					
05	Sterilization start time  Sterilization end time					
06						
	Cycle end time					
07	Performed By					
08	Checked By					
Checked By (Production) Sign/Date:			(Qua	Verified By (Quality Assurance) Sign/Date		
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#### 7.8 HEAT PENETRATION STUDY H.P.H.V. (MINIMUM GARMENT LOADED CHAMBER)

Test Instrument Name				
Make				
Sensors Type & Quantity				
Calibration done Date				
Calibration due Date				
Type of cycle	High pressure high vacuum cycle			
<b>Equipment Name</b>		<b>Equipment ID</b>		
<b>Equipment Make</b>		<b>Equipment Location</b>		

#### **OBSERVATION OF CYCLE PARAMETER**

Parameters	Set Value	Observed Value				
rarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
Cycle Start Date						
Cycle Start Time						
Pre Vacuum	- 0.600 Bar					
Pre Pressure	0.500 Bar					
No. of Pre pulses	3 Nos.					
Pre Pressure up	0.700 Bar					
Pre Pressure down	0.300 Bar					
No. of pulses	5 Nos.					
Pre pressure down final	0.600 Bar					
Small valve set point	120.0 °C					
Sterilization Hold Temperature	121.4 °C					



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Parameters	Set Value	Observed Value				
Tarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
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	-0.500 Bar					
Post vacuum hold time	5 Minute					
Post pressure	-0.100 Bar					
No. of post pulses	3 Nos.					
Process End Pressure	-0.040 Bar					
Cycle End Date & Time						
Cycle End Time						

Checked By (Production) Sign/Date:	Verified By (Quality Asso Sign/Date	urance)
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	Reviewed By	
	(Manager Qa Sign/Date:	······································



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#### 7.8.1 SUMMARY DETAIL OF STERILIZATION PROCESS

Date			
Sterilization Set temperature			
Time Process start			
Sterilization start time			
Sterilization end time			
Cycle end time			
Performed By			
Checked By			
	Time Process start  Sterilization start time  Sterilization end time  Cycle end time  Performed By  Checked By	Time Process start  Sterilization start time  Sterilization end time  Cycle end time  Performed By  Checked By	Time Process start  Sterilization start time  Sterilization end time  Cycle end time  Performed By

#### SUMMARY DETAIL OF STERILIZATION PROCESS (WITH EXTERNAL SENSORS)

S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1	Date			
2	Sterilization Set temperature			
3	Time Process start			
4	Sterilization start time			
5	Sterilization end time			
6	Cycle end time			
7	Performed By			
8	Checked By			

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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#### 7.8.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

7.0.2	Status of Cl		ndicator Strip	
	Status of Ci	- Chineur III	Surp	
S. No.	Observation	S. No.	Observation	Remark
Checked	Bv		Verified By	
(Product	ion)		(Quality Assuran	
Sign/Date	e:		Sign/Date	•••••
Inference	<u>.</u>			
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			Reviewed By (Manager QA)	
			Sign/Date:	



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#### 7.8.3 Fo CALCULATION:

Probe		ture (°C)		<b>alue</b>		Reduction	Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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#### 7.9 HEAT PENETRATION STUDY H.P.H.V. (MAXIMUM GARMENT LOADED CHAMBER)

Test Instrument Name			
Make			
Sensors Type & Quantity			
Calibration done Date			
Calibration due Date			
Type of cycle	High pressure high vacu	ium cycle	
<b>Equipment Name</b>		<b>Equipment ID</b>	
<b>Equipment Make</b>		<b>Equipment Location</b>	

#### **OBSERVATION OF CYCLE PARAMETER**

Parameters	Set Value	OF CICLETAKAN	<b>Observed Value</b>	
rarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date				
Cycle Start Time				
Pre Vacuum	- 0.600 Bar			
Pre Pressure	0.500 Bar			
No. of Pre pulses	3 Nos.			
Pre Pressure up	0.700 Bar			
Pre Pressure down	0.300 Bar			
No. of pulses	5 Nos.			
Pre pressure down final	0.600 Bar			
Small valve set point	120.0 °C			
Sterilization Hold Temperature	121.4 °C			



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Parameters	Set Value		Observed Value	
Tarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3
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	-0.500 Bar			
Post vacuum hold time	5 Minute			
Post pressure	-0.100 Bar			
No. of post pulses	3 Nos.			
Process End Pressure	-0.040 Bar			
Cycle End Date & Time				
Cycle End Time				

Checked By (Production) Sign/Date:	Verified By (Quality Assi Sign/Date	ırance)
Inference:		
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	Reviewed By (Manager QA Sign/Date:	



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S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
01	Date			
02	Sterilization Set temperature			
03	Time Process start			
04	Sterilization start time			
05	Sterilization end time			
06	Cycle end time			
07	Performed By			
U/	1 criorinea by			
	Checked By			
08	·	IZATION PROC	CESS (WITH EXTER	ENAL SENSORS
08 SU	Checked By	IZATION PROC	CESS (WITH EXTER	ENAL SENSORS  Cycle -3
08 S.No.	Checked By UMMARY DETAIL OF STERIL	_		
08 St.No.	Checked By  UMMARY DETAIL OF STERIL  Critical variables	_		
08 S.No. 01 02	Checked By  UMMARY DETAIL OF STERIL  Critical variables  Date	_		
08 S.No. 01 02 03	Checked By  UMMARY DETAIL OF STERIL  Critical variables  Date  Sterilization Set temperature	_		
08 S.No. 01 02 03 04	Checked By  UMMARY DETAIL OF STERIL  Critical variables  Date  Sterilization Set temperature  Time Process start	_		
08 S.No. 01 02 03 04 05	Checked By  UMMARY DETAIL OF STERIL  Critical variables  Date  Sterilization Set temperature  Time Process start  Sterilization start time	_		
07 08 S.No. 01 02 03 04 05 06	Checked By  UMMARY DETAIL OF STERIL  Critical variables  Date  Sterilization Set temperature  Time Process start  Sterilization start time  Sterilization end time	_		

(Production) Sign/Date:	(Quality Assurance) Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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#### 7.9.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

1.9.2	BSERVATION REPORT OF CHEWI		JICATON.						
	Status of Cl	nemical In	dicator Strip						
S. No.	Observation	S. No.	Observation	Remark					
Checked (Producti	•		Verified By (Quality Assuran Sign/Date	ce)					
			2- <b>g</b> -2						
Inference	<b>:</b>								
			Reviewed By						
			(Manager QA) Sign/Date:						
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#### **7.9.3** Fo CALCULATION:

Probe		ture (°C)	F <sub>o</sub> Value		<b>Spore Log Reduction</b>		Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status
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Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By
	(Manager QA) Sign/Date:



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## 7.10 HEAT PENETRATION STUDY IN FILLING MACHINE PART & ACCESSORY LOAD IN H.P.H.V PROCESS -11

Test Instrument Name			
Make			
Sensors Type & Quantity			
Calibration done Date			
Calibration due Date			
Type of cycle	High pressure high vacu	ıum cycle	
<b>Equipment Name</b>		<b>Equipment ID</b>	
Equipment Make		<b>Equipment Location</b>	

#### **OBSERVATION OF CYCLE PARAMETER**

Cot Volvo	Observed Value				
Set value	Cycle - 1	Cycle - 2	Cycle - 3		
- 0.600 Bar					
0.500 Bar					
3 Nos.					
0.700 Bar					
0.300 Bar					
5 Nos.					
0.600 Bar					
120.0 °C					
	0.500 Bar  3 Nos.  0.700 Bar  0.300 Bar  5 Nos.  0.600 Bar	- 0.600 Bar  0.500 Bar  3 Nos.  0.700 Bar  0.300 Bar  5 Nos.  0.600 Bar	Cycle - 1 Cycle - 2  - 0.600 Bar  0.500 Bar  3 Nos.  0.700 Bar  0.300 Bar  5 Nos.  0.600 Bar		



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### HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameters	Set Value	Observed Value				
rarameters	Set value	Cycle - 1	Cycle - 2	Cycle - 3		
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	-0.500 Bar					
Post vacuum hold time	5 Minute					
Post pressure	-0.100 Bar					
No. of post pulses	2 Nos.					
Process End Pressure	-0.040 Bar					
Cycle End Date & Time						
Cycle End Time						
Checked By (Production) Sign/Date:		Verified By (Quality Assurance) Sign/Date				
Inference:						
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Reviewed By (Manager QA) Sign/Date: .....



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# 7.10.1 SUMMARY DETAIL OF STERILIZATION PROCESS

S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1	Date			
2	Sterilization Set temperature			
3	Time Process start			
4	Sterilization start time			
5	Sterilization end time			
6	Cycle end time			
7	Performed By			
8	Checked By			
SU	MMARY DETAIL OF STERIL	ZATION PROCESS	(WITH EXTERNAL	SENSORS)

S. No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1	Date			
2	Sterilization Set temperature			
3	Time Process start			
4	Sterilization start time			
5	Sterilization end time			
6	Cycle end time			
7	Performed By			
8	Checked By			

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By
	(Manager QA) Sign/Date:



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7.10.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:								
Status of Chemical Indicator Strip								
S. No.	Observation	S. No.	Observation	Remark				
Checked (Producti Sign/Date			Verified By (Quality Assuran Sign/Date	ce)				
Inference	<b>:</b>							
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			Reviewed By (Manager QA)					
			Sign/Date:					



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# 7.10.3 Fo CALCULATION:

Sterili Tempera	ture (°C)	F <sub>o</sub> Value					Chemical Indicator
Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status
	Tempera	Sterilizing Temperature (°C) Maximum Minimum	Temperature (°C)	Temperature (°C)	Temperature (°C)	Temperature (°C)  For value  Spore Log Reduction	Temperature (°C)  Novimum Minimum Numerical RI Decired Actual Indicator

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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# 7.11 HEAT PENETRATION STUDY IN MANUFACTURING ACCESSORY LOAD IN STANDARD CYCLE

Test Instrument Name	
Make	
Sensors Type & Quantity	
Calibration done Date	
Calibration due Date	

Type of cycle	Standard cycle		
<b>Equipment Name</b>		Equipment ID	
Equipment Make		<b>Equipment Location</b>	

## **OBSERVATION OF CYCLE PARAMETER**

_		Observed Value					
Parameters	Set Value	Cycle - 1 Cycle - 2		Cycle - 3			
Cycle Start Date & Ti	ime						
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						
No. of pulses	5 Nos.						
Pre pressure down final	0.600 Bar						
Small valve SP	120 °C						
Sterilization Hold Temperature	121.4°C						



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		Observed Value						
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3				
Sterilization Hold time	30 Minute							
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	-0.040 Bar							
Cycle End Date								
Cycle End Time								

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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#### 7.11.1 SUMMARY DETAIL OF STERILIZATION PROCESS

S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1	Date			
2	Sterilization Set temperature			
3	Time Process start			
4	Sterilization start time			
5	Sterilization end time			
6	Cycle end time			
7	Performed By			
8	Checked By			

#### SUMMARY DETAIL OF STERILIZATION PROCESS (WITH EXTERNAL SENSORS)

S.No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
1	Date			
2	Sterilization Set temperature			
3	Time Process start			
4	Sterilization start time			
5	Sterilization end time			
6	Cycle end time			
7	Performed By			
8	Checked By			

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By (Manager QA) Sign/Date:



#### 7.11.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip									
S. No.	Observation	S. No.	Observation	Remark					
Checked By (Production) (Production) (Quality Assurance) Sign/Date: Sign/Date									
Inference	<b>:</b> :								
	Reviewed By (Manager QA) Sign/Date:								



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## **7.11.3 Fo CALCULATION:**

Sterilizing Townserveture (9C)		F <sub>o</sub> V	Value Spore Log Red		Reduction	Biological	Chemical	
Probe No	Temperature (°C)  Maximum Minimum		Numerical BI		Desired Actual		Indicator	Indicator
140	Wiaximum	1VIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	Numerical	DI	Desired	Actual	Status	Status
Checked I		I	I			Verified		
(Production							Assurance)	
Sign/Date Inference:		• • • • • • •				Sign/Da	ate	• • • • • • • • • • •
mierence:								
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**Test Instrument Name** 

# PERFORMANCE QUALIFICATION REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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# 7.12 HEAT PENETRATION STUDY IN DISINFECTAT FILTRATION LOAD IN STANDARD LOAD

Make			
Sensors Type & Quantity			
<b>Calibration done Date</b>			
Calibration due Date			
Type of cycle	Standard Load		
<b>Equipment Name</b>		Equipment ID	
<b>Equipment Make</b>		<b>Equipment Location</b>	

#### **OBSERVATION OF CYCLE PARAMETER**

_			Observed Value	
Parameters	Parameters Set Value		Cycle - 2	Cycle - 3
Cycle Start Date & Ti	ime			
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			
No. of pulses	5 Nos.			
Pre pressure down final	0.600 Bar			
Small valve SP	120 °C			



**STERILIZER** 

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		Observed Value				
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3		
Sterilization Hold Temperature	121.4°C					
Sterilization Hold time	30 Minute					
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	-0.040 Bar					
Cycle End Date						
Cycle End Time						

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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SU	MMARY DETAIL OF STERIL	IZATION PROC	CESS	
Sr No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
01	Date			
02	Sterilization Set temperature			
03	Time Process start			
04	Sterilization start time			
05	Sterilization end time			
06	Cycle end time			
07	Performed By			
08	Checked By			
SU	MMARY DETAIL OF STERIL	ZATION PROC	CESS (WITH EXTER	NAL SENSORS)
Sr No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
Sr No.	Critical variables  Date	Cycle -1	Cycle -2	Cycle -3
		Cycle -1	Cycle -2	Cycle -3
01	Date	Cycle -1	Cycle -2	Cycle -3
01 02	Date Sterilization Set temperature	Cycle -1	Cycle -2	Cycle -3
01 02 03	Date Sterilization Set temperature Time Process start	Cycle -1	Cycle -2	Cycle -3
01 02 03 04	Date Sterilization Set temperature Time Process start Sterilization start time	Cycle -1	Cycle -2	Cycle -3
01 02 03 04 05	Date Sterilization Set temperature Time Process start Sterilization start time Sterilization end time	Cycle -1	Cycle -2	Cycle -3
01 02 03 04 05 06	Date Sterilization Set temperature Time Process start Sterilization start time Sterilization end time Cycle end time	Cycle -1	Cycle -2	Cycle -3

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Data.



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## 7.12.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip							
S. No.	Observation	S. No.	Observation	Remark			
Checked (Producti Sign/Date			Verified By (Quality Assuran Sign/Date	ce)			
Inference							
			Reviewed By (Manager QA) Sign/Date:				



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# 7.12.2 Fo CALCULATION:

Probe	Sterili Temperat	ture (°C)			Spore Log Reduction		Biological	Chemical
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	Indicator Status
	ı	1	ı					

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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#### 7.13 HEAT PENETRATION STUDY IN MIXED LOAD IN STANDARD PROCESS

Test Instrument Name			
Make			
Sensors Type & Quanti	ity		
<b>Calibration done Date</b>			
Calibration due Date			
Type of cycle	Standard cycle		
Equipment Name		Equipment ID	
<b>Equipment Make</b>		<b>Equipment Location</b>	

# **OBSERVATION OF CYCLE PARAMETER**

	a		Observed Value	
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
Cycle Start Date & Ti	me			
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			
No. of pulses	5 Nos.			
Pre pressure down final	0.600 Bar			
Small valve SP	120 °C			
Sterilization Hold Temperature	121.4°C			
Sterilization Hold time	30 Minute			



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	G A V I		<b>Observed Value</b>	
Parameters	Set Value	Cycle - 1	Cycle - 2	Cycle - 3
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	0.040 Bar			
Cycle End Date				
Cycle End Time				

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



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#### 7.13.1 SUMMARY DETAIL OF STERILIZATION PROCESS

Sr. No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
01	Date			
02	Sterilization Set temperature			
03	Time Process start			
04	Sterilization start time			
05	Sterilization end time			
06	Cycle end time			
07	Performed By			
08	Checked By			

# SUMMARY DETAIL OF STERILIZATION PROCESS (WITH EXTERNAL SENSORS)

Sr. No.	Critical variables	Cycle -1	Cycle -2	Cycle -3
01	Date			
02	Sterilization Set temperature			
03	Time Process start			
04	Sterilization start time			
05	Sterilization end time			
06	Cycle end time			
07	Performed By			
08	Checked By			

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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#### 7.13.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

7.13.2 U	BSERVATION REPORT OF CHEW		DICATOR.	
	Status of C	hemical In	ndicator Strip	
S. No.	Observation	S. No.	Observation	Remark
Checked (Product			Verified By (Quality Assuran	ce)
Sign/Date	e:		Sign/Date	
Inference	2:			
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			(Manager QA)	
			Sign/Date:	•••••



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# 7.13.3 Fo CALCULATION:

Probe	Sterilizing Temperature (°C)		F <sub>o</sub> Value			Reduction	Biological Indicator	Chemical Indicator
No	Maximum	Minimum	Numerical	BI	Desired	Actual	Status	Status

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date
Inference:	
	Reviewed By
	· · · · · · · · · · · · · · · · · · ·
	(Manager QA)
	Sign/Date:



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## 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		
Vacuum Leak Test (Hot)		
Heat Distribution Study in Empty Chamber H.P.H.V process		
Heat Distribution Study in Empty Chamber standard process		
Heat Penetration Study in Garment Minimum Loaded		
Heat Penetration Study in Garment Maximum Load		
Heat Penetration Study in Filling Machine parts & Accessories load		
Heat Penetration Study in Mixed Load		
Heat Penetration Study in Manufacturing accessories load		
Heat Penetration Study in Filtration accessories load.		
Post vacuum		
Checked By		Verified By
(Production)		(Quality Assurance)
Sign/Date:		Sign/Date
Inference:		
		Reviewed By
		(Manager QA) Sign/Date:



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## 9.0 DOCUMENTS TO BE ATTACHED:

- Biological Indicator Incubation Report.
- Calibration Certificates for Data Logger.
- Calibration Certificates of Sensors.
- Printouts of Thermograph of all the cycles from HPHV Steam sterilizer for time, temperature and pressure profile.

10.0	NON COMPLIANCE:
11.0	DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:
12.0	CHANGE CONTROL, IF ANY:



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13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY ):
14.0	CONCLUSION:
15.0	RECOMMENDATION:
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# PERFORMANCE QUALIFICATION REPORT FOR

# HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

PROTOCOL No.:

#### **16.0 ABBREVIATIONS:**

QC : Quality Control

DQ : Design Qualification

IQ : Installation Qualification

OQ : Operational Qualification

PQ : Performance Qualification

CQA : Corporate Quality Assurance

MOC : Material of Construction

NLT : Not Less Than

Sec. : Seconds

SS : Stainless Steel

ID. : Identification

ID : Inner Diameter

°C : Degree centigrade

HPHV : High pressure high vacuum

PVT : Private

Ltd. : Limited

No. : Number

SAL : Sterility log reduction

#### 17.0 POST APPROVAL:



#### **INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### **REVIEWED BY:**

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

#### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			