



PHARMA DEVILS

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

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



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1.0 REPORT PRE – APPROVAL:

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
Quality Assurance	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Review of Report.• To co-ordinate and support Performance Qualification Activity.
Quality Control	<ul style="list-style-type: none">• Review of Report.• Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none">• Reviewing of qualification Report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.
External Qualification Agency (if Applicable)	<ul style="list-style-type: none">• Performance of qualification activity as per protocol



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5.0 EQUIPMENT DETAILS:

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



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6.0 PRE – QUALIFICATION REQUIREMENTS:

Record the observations for documents in the below mentioned table.

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

**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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FOR
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7.0 TESTS AND CHECKS:

7.1 VACUUM LEAK TEST:

VACUUM LEAK TEST DETAILS

Equipment Name				
Equipment Make				
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				
Cycle Completed				

**Checked By
(Production)**

Sign/Date:

**Verified By
(Quality Assurance)**

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Inference:

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**Reviewed By
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Sign/Date:



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PROTOCOL No.:

7.2 WARM UP CYCLE:

WARM UP CYCLE TEST DETAILS

Equipment Name				
Equipment Make				
Equipment ID No.				
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				

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(Production)
Sign/Date:

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(Quality Assurance)
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7.3 VACUUM LEAK TEST IN HOTCONDITION:

VACUUM LEAK TEST IN HOTCONDITION

Equipment Name				
Equipment Make				
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			



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Delay before hold	3 min			
Vacuum hold time	10 min			
Acceptable leakage	0.013 bar			
Process end pressure	-0.030 bar			
Cycle Completed				

**Checked By
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Sign/Date:

**Verified By
(Quality Assurance)**

Sign/Date:.....

Inference:

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Sign/Date:



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PROTOCOL No.:

7.4 BOWIE - DICK TEST:

Bowie Dick Test Details

Equipment Name	
Equipment Make	
Equipment ID No.	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed Value		
		Cycle - 1	Cycle - 2	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		
		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
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Verified By
(Quality Assurance)
Sign/Date:.....

Inference:

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Sign/Date:



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PROTOCOL No.:

**Attach
Bowie - Dick Test
Indicator**

Observation:

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:.....

Inference:

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Reviewed By

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Sign/Date:



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PROTOCOL No.:

**Attach
Bowie - Dick Test
Indicator**

Observation:

**Checked By
(Production)**

Sign/Date:

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PROTOCOL No.:

**Attach
Bowie - Dick Test
Indicator**

Observation:

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:.....

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PROTOCOL No.:

7.5 EMPTY CHAMBER HEAT DISTRIBUTION STUDY FOR HPHV PROCESS -1

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

Type of cycle	High pressure high vacuum cycle		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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		
		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:

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PROTOCOL No.:

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:

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7.6 EMPTY CHAMBER HEAT DISTRIBUTION STUDY FOR HPHV PROCESS -1I

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

Type of cycle	High pressure high vacuum cycle		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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		
		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				

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

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

Inference:

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**Reviewed By
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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			

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

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

Inference:

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**Reviewed By
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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		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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 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			

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:

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PROTOCOL No.:

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		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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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PROTOCOL No.:

Parameters	Set Value	Observed 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:.....

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PROTOCOL No.:

7.8.1 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)
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(Quality Assurance)
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PROTOCOL No.:

7.8.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation	Remark

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

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

Inference:

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**Reviewed By
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Sign/Date:**



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PROTOCOL No.:

7.8.3 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual		

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

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

Inference:
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PROTOCOL No.:

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 vacuum cycle		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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		
		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:

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**Reviewed By
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Sign/Date:**



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

PROTOCOL No.:

7.9.1 SUMMARY DETAIL OF STERILIZATION PROCESS

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			
08	Checked By			

SUMMARY DETAIL OF STERILIZATION PROCESS (WITH EXTERNAL SENSORS)

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			
08	Checked By			

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

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

Inference:

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



PHARMA DEVILS

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

PROTOCOL No.:

7.9.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation	Remark

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:.....

Inference:

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Reviewed By

(Manager QA)

Sign/Date:



PHARMA DEVILS

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

PROTOCOL No.:

7.9.3 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual		

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

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

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



PHARMA DEVILS

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

PROTOCOL No.:

**7.10 HEAT PENETRATION STUDY IN FILLING MACHINE PART & ACCESSORY LOAD IN
H.P.H.V PROCESS -I1**

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

Type of cycle	High pressure high vacuum cycle		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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			



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

PROTOCOL No.:

Parameters	Set Value	Observed 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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**PERFORMANCE QUALIFICATION REPORT
FOR
HIGH PRESSURE HIGH VACUUM STEAM
STERILIZER**

PROTOCOL No.:

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			

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:

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



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

PROTOCOL No.:

7.10.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation	Remark

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

PROTOCOL No.:

7.10.3 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual		

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

PROTOCOL No.:

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		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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			



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

PROTOCOL No.:

Parameters	Set Value	Observed 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:

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Reviewed By

(Manager QA)

Sign/Date:



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

PROTOCOL No.:

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:

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Reviewed By
(Manager QA)
Sign/Date:



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

PROTOCOL No.:

7.11.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation	Remark

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

PROTOCOL No.:

7.11.3 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual		

Checked By
(Production)
Sign/Date:

Inference:

Verified By
(Quality Assurance)
Sign/Date:

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Reviewed By
(Manager QA)
Sign/Date:



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

PROTOCOL No.:

**7.12 HEAT PENETRATION STUDY IN DISINFECTANT FILTRATION LOAD IN STANDARD
LOAD**

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

Type of cycle	Standard Load		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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			



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

PROTOCOL No.:

Parameters	Set Value	Observed 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:

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



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

PROTOCOL No.:

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:

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



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

PROTOCOL No.:

7.12.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation	Remark

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

PROTOCOL No.:

7.12.2 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual		

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

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

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



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

PROTOCOL No.:

7.13 HEAT PENETRATION STUDY IN MIXED LOAD IN STANDARD PROCESS

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

Type of cycle	Standard cycle		
Equipment Name		Equipment ID	
Equipment Make		Equipment Location	

OBSERVATION OF CYCLE PARAMETER

Parameters	Set Value	Observed 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			



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

PROTOCOL No.:

Parameters	Set Value	Observed 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				

**Checked By
(Production)**

Sign/Date:

**Verified By
(Quality Assurance)**

Sign/Date:.....

Inference:

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**Reviewed By
(Manager QA)**

Sign/Date:



PHARMA DEVILS

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

PROTOCOL No.:

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:

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Reviewed By
(Manager QA)
Sign/Date:



PHARMA DEVILS

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

PROTOCOL No.:

7.13.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation	Remark

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

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

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



PHARMA DEVILS

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

PROTOCOL No.:

7.13.3 F₀ CALCULATION:

Probe No	Sterilizing Temperature (°C)		F ₀ Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual		

Checked By (Production)
Sign/Date:
Inference:

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

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Reviewed By (Manager QA)
Sign/Date:



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

PROTOCOL No.:

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
(Production)**

Sign/Date:

**Verified By
(Quality Assurance)**

Sign/Date:.....

Inference:

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**Reviewed By
(Manager QA)**

Sign/Date:



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

PROTOCOL No.:

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:

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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
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:



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

PROTOCOL No.:

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)			