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

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

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL PRE – 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)			

PERFORMANCE QUALIFICATION PROTOCOL 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 test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance qualification for the HPHV Steam sterilizer, installed in Unit Preparation & Sterilization room.
- This Protocol will define the Heat Penetration Study during Maximum Load with Decron Bag / Tyvek Bag and documentation used to qualify the HPHV Steam Sterilizer.

PERFORMANCE QUALIFICATION PROTOCOL FOR BIO-CHALLENGE STUDY FOR HIGH PRESSURE HIGH VACUUM 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 Protocol cum Report:

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

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

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

5.0 EQUIPMENT DETAILS:

Equipment Name	HPHV Steam Sterilizer
Equipment	
Serial No.	
Capacity	675 L.
Size	750 x750 x1200 mm
Manufacturer's Name	
Supplier's Name	
Location of Installation	Unit preparation & Sterilization Room

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

6.0 SYSTEM DESCRIPTION:

The sterilizer manufactured by M/s Machine Fabrik is designed for the best possible adaptation to the need of sterilization. The High Pressure High Vacuum Sterilizer can be efficiently used to perform two type of sterilization –

- Standard Steam sterilization
- High Pressure High Vacuum Sterilization
- The chamber of the sterilizer can be tested by the following methods:
- Chamber Leak Test
- Bowie Dick test

Standard HPHV is a Jacketed Pressure Vessel. The Standard Steam Sterilization cycle is initiated by introducing Steam into the Jacket. This essentially aids in Preheating the Chamber and Effective Utilization of Heat Energy.

When a Particular Pressure inside the Jacket is achieved, Steam is introduced into the chamber. Air being heavier than Steam is displaced by Gravity Displacement Method which ensures Uniform Steam Distribution and Penetration. The equipment is also provided with Steam Traps with Air Vent to ensure Maximum Air Removal and Steam Condensate without allowing steam to pass through it.

As the Temperature of the Chamber increases, and reaches to the Sterilization Temperature, the control system in place controls this temperature for the Sterilization Time.

After the sterilization hold period is completed, steam from the chamber is exhausted to bring the chamber pressure to atmosphere.

The High pressure High Vacuum Steam Sterilization Process consists of following phases:-

- Vacuum steam pulsing
- Heat up
- Sterilization hold
- Vacuum drying
- Sterile air in

The Standard Steam Sterilization Process consists of following phases: -

- Heat up
- Sterilization hold
- Exhaust

A double door Steam Sterilizer is an industrial steam sterilizer especially designed for:

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

- Steam Sterilization of Garments, Mopping pads, Gloves.
- Steam Sterilization of Filtration Accessories.
- Steam Sterilization of Filling Machine Components, Manufacturing Accessories etc.
- Steam Sterilization of Pressure vessel
- Steam Sterilization of Media.(During media fill)

HIGH PRESSURE HIGH VACUUM STEAM STERILIZATION:

- In this process, the steam is introduced into the jacket which insures preheating of chamber and effective utilization of heat energy. As the pressure inside chamber reaches a set level, almost 100% removal of air is ensured by creating vacuum and pulsing in steam in the chamber. The steam/ vacuum pulsing not only ensure absence of air pockets and cold spots but also ensure uniform temperature distribution.
- The vacuum is created with the help of water ring type vacuum pump.
- After fixed no. of pulses, the steam pressure in the chamber is increased till the sterilization temperature is reached. The control system in place then controls this chamber temperature for the sterilization time.
- After the sterilization hold period is completed, vacuum up to a pre-determined level is created in the chamber. When this vacuum level is reached, the control system ensures that the vacuum is maintained for the specified time. The vacuum created at this stage ensures drying of the charge inside the chamber .After the vacuum drying time is complete, then chamber is brought to atmospheric pressure by injection of sterile air.

  The sterile charge is then unloaded from the chamber. Thus, the high pressure high vacuum steam sterilization cycle consists of following phases:-

- Vacuum steam pulsing
- Heat up
- Sterilization Hold
- Vacuum Drying
- Sterile Air In

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

7.0 REASON FOR RE-QUALIFICATION:

- Periodically as per Qualification Frequency

8.0 SITE OF STUDY:

- HPHV Steam Sterilizer.

9.0 FREQUENCY OF RE-QUALIFICATION:

- After any major breakdown or after major modification.
- After Change of Location.
- 6 Month ± one Month & Minimum Load once in a year ± one Month

10.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents and observations shall be recorded in the performance qualification report.

10.1 TEST EQUIPMENT:

S.No.	Test Instrument
1.	Biological Indicator 10^6 spores i.e. *Geobacillus stearothermophilus* must be checked for spore population.
2.	Chemical Indicator (Steam Clox).

10.2 Biological Indicator detail should be mentioned in Performance Qualification Report.

10.3 TRAINING OF EXECUTION TEAM:

Provide the training to a team for the execution of protocol before execution of the same. Record of training shall be recorded in Performance Qualification Report.

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

11.0 TESTS AND CHECKS:

- The autoclave will be considered validated on successful completion of the following tests.
- Vacuum Leak test (1 cycles)
- Bowie-Dick Test (1 cycles)
- Loaded chamber heat penetration studies for each sterilization load of fixed loading pattern, with, Bio-challenge studies using ***Geobacillus Stearothermophillus*** spore ampoule (containing 10^6 or more spore) during the heat penetration studies.

Load Pattern:

- Vacuum Leak Test (1 Cycles)
- Bowie-Dick Test (1 Cycles)
- Heat Penetration Study Standard Process (Mfg accessories load-Maximum load) (1 Cycle)
- Heat Penetration Study Standard Process (Orientator load) (1 Cycle)
- Heat Penetration Study H.P.H.V.-01 (Garment –Maximum load) (1 Cycle)
- Heat Penetration Study H.P.H.V.-01. (Inner garments maximum load) (1 Cycle)
- Heat Penetration Study H.P.H.V.-Process 02. (Machine parts-Maximum load) (1 Cycle).
- Heat Penetration Study H.P.H.V.-Process 02. (Filtration accessories-Maximum load) (1 Cycle).
- Biological/ Bacteriological evaluation in each cycle of Heat Penetration Studies.

11.1 VACUUM LEAK TEST :

11.1.0 Objective

To verify the Leakage in Sterilization Chamber during Vacuum Hold when the Sterilization Chamber is empty.

11.1.1 Procedure

- Operate the equipment as per SOP on operation of HPHV Steam sterilizer

Set the following parameters

Pre Vacuum	=	- 0.700 Bar
Delay before Hold	=	3 Minute
Vacuum Hold Time	=	10 Minute
Acceptable Leakage	=	NMT 0.013 Bar
Process End Pressure	=	-0.030 Bar

- Check the pressure of the chamber initially.

- Record the pressure of the chamber after three min. of getting start the autoclave.
- Record the pressure of the chamber after ten min. of getting start the autoclave.
- Measure the difference between the pressures.
- Calculate the difference of pressure per min.
- Each Cycle Should be Performed at one time

11.1.2 Acceptance Criteria

Actual vacuum leakage should be not more than **0.013 Bar.**

11.1.3 Evaluation of Result

If Actual vacuum leakage is not within the specified limit, check the Gasket & other joints of the chamber. If the Minimum vacuum leakage is not achievable, Gasket shall be changed or any other appropriate measures be taken to achieve the acceptance criteria.

11.2 BOWIE-DICK TEST:

11.2.0 Objective

- To ensure that the Vacuum Pulses applied before the Sterilization Hold Period are sufficient to remove the Entrapped Air or Non-Condensable Gases so as to facilitate rapid and even Steam Penetration into all parts of the load and maintaining these conditions for the Specified Temperature Hold Time (660 Sec. at 121.4°C).
- If air is present in the chamber, it will collect within the Bowie-Dick Test Pack as a Bubble. The indicator in the region of the Bubble will be of different color as compared to the color on the remaining part of the test paper, because of a lower temperature, lower moisture level or both. In this condition the cycle parameters to be reviewed and the normal sterilization cycles to be modified accordingly.

11.2.1 Procedure

- Operate the equipment as per SOP. on operation of HPHV Steam sterilizer
- Set the following parameters in PLC.

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 bar
Pre pressure	To break the vacuum with steam	0.500 bar
No. of pre pulses	To repeat the vacuum pressure pulses	3 Nos.
Pre pressure up	For pressure pulses to improve heat distribution	0.700 bar
Pre pressure down	For pressure pulses to improve heat distribution	0.300 bar
Pre pressure down final	--	0.600 bar
Small valve sp	--	120.0 °C
Ster. Hold temp.	Sterilization	121.4°C
Ster. Hold time	To hold the sterilization period as per the set time	11 min
Temperature control band	To control max. & min. level of temperature during sterilization period	0.2 ° C
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC

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

Parameter	Purpose	Set Value
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.9ºC
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5ºC
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Place one Bowie-Dick Test Pack in the center (Near Drain) of the sterilization chamber, supported approximately 100 to 200 mm above the sterilization chamber base as given in Figure 1.
- The printout taken during the Bowie-Dick test cycle & the Bowie-Dick test indicator should be attached in the Performance Qualification Report.
- Compile the observations made during the test for complete evaluation of the system.

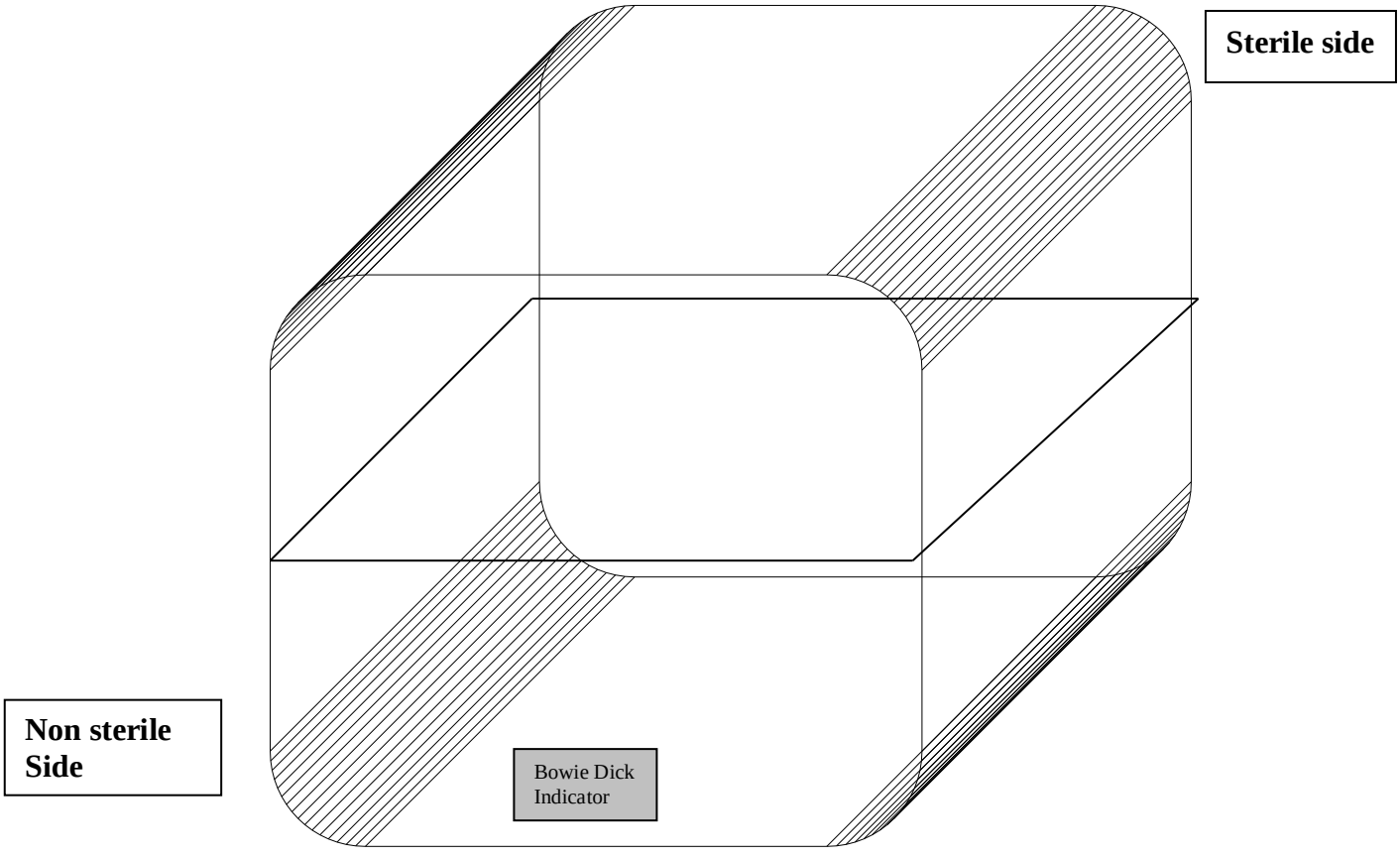

Figure 1: Location of Bowie Dick test Indicator inside the chamber at Drain Point.

11.2.2 Acceptance Criteria

The Bowie-Dick Test Indicator should show a uniform color change. No change, Non-Uniform Change and / or Air Entrapment (bubble) Spot on the Test Pack indicates inadequate air removal from the sterilization chamber.

11.2.3 Observation :

Record the observations in Performance Qualification Report.

11.2.4 Evaluation of Result

Uniform color changes of Bowie Dick test Indicator shows the absence of Entrapped air or non Condensable gases inside the chamber. In case of Entrapped air or non condensable gases inside the chamber, vacuum leak test shall be rechecked and also check other joints. After taking proper Corrective measures, Bowie Dick Test shall be re-checked and cycle also be run again.

11.3 HEAT PENETRATION STUDY:

11.3.0 Objective

- To ensure that the steam is sufficiently penetrating into the innermost portions of the load subjected for Sterilization to achieve desired Temperature of 121.4°C during the whole Sterilization Hold Period with Steam Pressure of 1.2 to 1.4 Kg/Cm^2.
- To ensure that if Sterilization Temperature (121.4°C) is not achieved throughout the cycle, load configuration or size of the load has to be reviewed and Sterilization Cycles to be repeated.
- To ensure that temperature spread within the range of 121.4°C to 124°C during Sterilization Hold Period indicate that, Uniform Heating Process which is achieved in the Empty Chamber Heat Distribution Study is not affected by load. There could be the possibility of lag period for attaining 121.4°C during heat penetration trials as the probes are placed deep into the load.
- To ensure that any location(s) where the probes is placed, achieving Minimum Sterilization Temperature of 121.4°C during Sterilization Temperature Hold Period will be considered as Cold Spot.
- Heat Penetration studies shall be carried out with the following different loads:

Heat Penetration studies.

- Mfg accessories load-Minimum load Standard process
- Mfg accessories load-Maximum load Standard process
- Orientator load Standard process

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

- Garment –minimum load HPHV 1
- Garment –Maximum load HPHV 1
- Inner garments –minimum load HPHV 1
- Inner garments maximum load HPHV 1
- Machine parts-Minimum load HPHV 2
- Machine parts-Maximum load HPHV 2
- Filtration accessories-Minimum load HPHV 2
- Filtration accessories-Maximum load HPHV 2

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

11.4 HEAT PENETRATION STUDY:

A) Load Details:

LOAD I- MFG ACCESSORIES -MAXIMUM LOAD (STANDARD PROCESS)

Load Configuration	No Of Articles
Manufacturing Accessories Load	
SS Mug - 5 Lit.	2 Nos.
SS Mug - 2 Lit.	1 Nos.
SS Mug - 1 Lit.	2 Nos.
SS hose pipe (NMT 3 Mtr)	02 Nos
Air /N2/Vent filter (5 inch)	06 Nos.
Liquid Chemical	02 Nos.
Tool Box	01 No.
SS Spoon	04 Nos.
Silicon tubing(NMT 02 Mtr)	02 Nos
Sampling rod	01 Nos
SS Container	03 Nos
Measuring Cylinder(Glass)-1 Lit	01 Nos
Measuring Cylinder(Glass)-2 Lit	01 Nos

LOAD II-ORIENTATOR LOAD (STANDARD PROCESS)

Load Configuration	No. Of Articles
ORIENTATOR LOAD	
Orientator	01 No.

LOAD III- GARMENT MAXIMUM LOAD (Process—HPHV 1):

Load Configuration	No Of Articles
Maximum Garment Load	
Antistatic Sterile Garments Boiler suit+ Head Gear + Booties+ Eye Goggle	30 set
Mopping pads	10 Nos.

Load IV—INNER GARMENT MAXIMUM LOAD (Process—HPHV 1)

Load Configuration	No Of Articles
Inner Garment Maximum Load	
Inner Garments(Upper+Lower+Cap+Booties)	30 set

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

LOAD V- MACHINE PARTS-MAXIMUM LOAD (PROCESS-HPHV 2)

Load Configuration	No Of Articles
Filling Machine Parts & Accessory	
Manifold Filling	1 Nos
Filling Needle – Filling Machine Nozzle Mounting Bracket	6 Nos
Silicon Tubes in SS container(NMT 2 Mtr)	31 Nos
Chute – Sterilized Bottles	01 Nos
Hopper – Dropper	01 Nos
Chute – Dropper	01Nos
Dropper Pressing Assembly	08 Nos
Hopper – Screw Cap	01 Nos
Chute – Screw Cap	01 Nos
Capping Head Assembly	08 Nos
Nut of Hoppers	08 Nos
Scissor	02 Nos
SS Forceps	04 Nos
Nitrogen Gas Flushing Nozzles	13 Nos
SS connector	06 Nos
SS jug	04 Nos

LOAD VI-FILTRATION ACCESSORIES MAXIMUM LOAD (PROCESS-HPHV 2)

Load Configuration	No Of Articles
Filtration Accessories	
Filter Housing(10 inch)	02 No.
Pressure vessel -100 Lit.	01 No.
Autoclavable IPA bottle	10 Nos.
SS Mug. 1 Lit.	01 No.
SS Mug. 2 Lit.	01 No.
SS Mug. 5 Lit.	01 No.
Silicon tube (NMT 02 Mtr)	04 Nos.
Autoclavable Paper	06 Nos
Bio Barrier Paper	04 Nos
Mopping bucket	03 Nos.
Mop head	01 Nos.
S S Container	04 Nos

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

MATERIAL TO BE PACKED IN DECRON BAG/TYVEK BAG DURING HEAT PENETRATION STUDY AS PER GIVEN DETAIL:

Material to be packed in one Decrcon/Tyvek bag	Material/Article detail	Nos.
Decron bag	Orientator(Hopper-Sterilized bottle)	01 Nos
Decron bag	Hopper – Dropper	01 Nos
Decron Bag	Hopper – Screw Cap	01 Nos
Decron bag	Filter housing 10 inch	01 No
Tyvek bag	Manifold Filling	01 Nos
	Filling Machine Nozzle	06 Nos
	Silicon Tubes in SS container(NMT 2 Mtr)	12 Nos
	SS connector	06 Nos
Tyvek bag	Chute – Sterilized Bottles	01 Nos
Tyvek bag	Chute – Dropper	01Nos
Tyvek bag	Dropper Pressing Head Assembly	08 Nos
Tyvek bag	Chute – Screw Cap	01 Nos
Decron Bag	Capping Head Assembly	08 Nos
Tyvek bag	Nut of Hoppers	08 Nos
Tyvek bag	Scissor	02 Nos
Tyvek bag	SS Forceps	04 Nos
Tyvek bag	Nitrogen Gas Flushing Nozzles with Silicon tube	Nozzle-06 Nos Silicon tube-06 Nos Mounting bracket-01 No
Tyvek bag	Nitrogen Gas Flushing Nozzles with Silicon tube	Nozzle-07 Nos Silicon tube-07 Nos Mounting bracket-01 No
Tyvek bag	SS jug	01 Jug in one bag
Tyvek bag	Silicon Tubes (NMT 2 Mtr)	01 No
Tyvek bag	Autoclavable IPA bottle	01 bottle in one bag
Tyvek bag	Mop head	01 Nos
Tyvek bag	Autoclavable Paper	06 Paper in one bag
Tyvek bag	Bio barrier paper	04 paper in one bag
Tyvek bag	TC clamp with Silicon gasket	TC clamp-04 Nos Silicon gasket-04 Nos

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

B) Equipment / Instrument Used:

- Biological Indicators
- Chemical Indicators (Steam Clox)

C) Procedure

- Conduct the Bio-challenge study with loaded chamber cycles with Chemical & Biological Indicators.
- Switch ON the MAINS of the control panel and set the respective parameters according to cycles &.transfer the load to sterilizer and keep the biological indicator & steam clox strip with in the innermost area of each load. Close the door of sterilizer and start the cycle as per for operating Instructions.
- Select the suitable parameter from PLC.
- Simultaneously insert new chart in chart recorder provided on the control panel of an autoclave .Run the cycle as per SOP for operating instruction.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators and send to microbiology for incubation.
- Compile the data generated during the Re-qualification, for complete evaluation of the system.

Location of the Biological Indicator & Chemical indicator in Loaded Chamber

Location No.	Location in the Chamber
S1	In the drain of the autoclave chamber. T1
S2	Adjacent To Autoclave Inbuilt Sensor T2
S3	Adjacent To Autoclave Inbuilt Sensor T3
S4	Adjacent To Autoclave Inbuilt Sensor T4
S5	Adjacent To Autoclave Inbuilt Sensor T5
S6	Innermost part of the load
S7	Innermost part of the load
S8	Innermost part of the load
S9	Innermost part of the load
S10	Innermost part of the load
S11	Innermost part of the load
S12	Innermost part of the load

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

D) Acceptance Criteria

- The chemical indicators should change the color from Pink to Green.
- All Biological Indicators should show no growth after incubation.

E) Observation :

Record the observations in Performance Qualification Report.

F) Evaluation of Result

- The colour of chemical indicator should be change uniformly from pink to green. & all biological indicators should show no growth.

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

11.5 BIOLOGICAL CHALLENGE TEST

A) OBJECTIVE:

- To demonstrate the degree of process lethality provided by the Sterilization cycle.

B) EQUIPMENT / INSTRUMENT USED:

- Biological Indicator (spores of ***Geobacillus stearothermophilus***).

C) PROCEDURE

- After determining the worst case items and worst locations i.e. cold spots, challenge these items/locations with biological indicator (spores of *Geobacillus stearothermophilus)*.
- Carry out the microbial challenge study concurrently with loaded chamber Heat Penetration studies.
- Place, previously population validated biological indicator ampoules of specified 10^6 Spores per unit along with the probes at the same location, within each load type of the specified load pattern, as in the loaded chamber heat penetration studies. Retain two biological indicators as positive control.
- Operate the autoclave as per SOP on operation of HPHV Steam sterilizer.
- Record the chamber temperature and pressure for every minute.
- Simultaneously start the recording with data logger and take printouts.
- At the end of the cycle Switch OFF the autoclave.
- Remove the biological indicator with the help of safety gloves and incubate all exposed & unexposed BI.
- After incubation observe the indicator for growth. (+ve when purple color change to yellow color, -ve when purple color remain as such).
- If indicator shows positive results increase holding time and validate the cycle for this period to get minimum Sterility Assurance Level (SAL) 10^{-6}.Run three consecutive cycles.
- Biological Indicator Detail & testing result are Mention in performance Qualification Report by Manually.

D) ACCEPTANCE CRITERIA:

- Visually observe the ampoules, test +ve when purple color change to yellow color, test -ve when purple color remain as such.
- If no evidence of growth observed in any of the inoculated tube and growth observed in positive control tube, the test meets the criteria to achieve the desired level of sterility.

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

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

S.No.	NAME OF TEST OR CHECK	ACCEPTANCE CRITERIA
1.	Vacuum Leak Test (Cold)	NMT 0.013 BAR
2.	Bowie-Dick Test	Uniform color changes of Bowie Dick test Indicator sho the absence of Entrapped air or non condensable gases inside the chamber
4.	Heat Penetration Study Standard Process Mfg accessories load-Maximum load Orientator load	• The chemical indicators should change the color from Pink to Green. • All Biological Indicators should show no growth after incubation.
5.	Heat Penetration Study HPHV Process.- 01 Garment –Maximum load Inner garments maximum load	
6.	Heat Penetration Study HPHV Process.- 02 Machine parts-Maximum load Filtration accessories-Maximum load	

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

13.0 REFERENCES:

The Principle References are as following:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.
- HTM 2010 Part-3 (Validation & Verification).
- EN285
- PDA Technical Report 01 (Sterilization by Moist Heat).

14.0 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 high pressure high vacuum steam sterilizer for time, temperature and pressure profile.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

°C	:	Degree Centigrade
BI	:	Biological Indicator
CI	:	Chemical Indicator
HPHV	:	High pressure high vacuum
Min.	:	Minute
NMT	:	Not more than
No.	:	Number
MRP	:	Master Performance Qualification Protocol
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
SS	:	Stainless steel