PERFORMANCE QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE

EQUIPMENT ID No.	**…….**
LOCATION	**Washing & Sterilization Area**
DATE OF QUALIFICATION	
SUPERSEDED PROTOCOL No.	**NIL**

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE	PROTOCOL No.:

1.0 PROTOCOL -APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- This protocol is designed to establish & provided the documentary evidence, to assure that the Vertical Autoclave, supplied by …… is suitable for sterilizing the loads. In addition, this validation Protocol is intended to assure the Sterilization Process of the items, when the equipment is operated in accordance with the established standard operating procedure to maintain reliability and repeatability.
- The purpose of this Protocol is to perform tests on the given equipment to check whether the equipment will perform reproducibly and consistently within its full dynamic range of operation according to manufacturer's specification and user's requirement.

3.0 SCOPE:

- This is an integrated document applicable to performance requalification for vertical Autoclave installed at Washing & Sterilization area.

4.0 RESPONSIBILITY:

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

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation and Approval of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Protocol.
Production	• Review & approval of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing/Analysis)
Engineering	• Review & Approval of Performance Qualification Protocol 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)	• Performance of qualification activity as per protocol

5.0 EQUIPMENT DETAILS:

Equipment Name	Vertical Autoclave
Equipment	
Manufacturer's Name	
Model	
Sr.No.	
Capacity	175 Ltr.
Supplier's Name	
Location of Installation	Washing & Sterilization Area

6.0 SYSTEM DESCRIPTION:

The instrument is a fully automatic autoclave controller. It is designed around a powerful micro-controller. As such, it is compact, very rugged and user-friendly. The field wiring is brought on to plug-in type of connectors, thereby reducing down time. The Man-Machine-Interface (MMI) consists of a 16 characters by 2line LCD display with back lit, 6 – keys membrane keypad.

The instrument accepts 1no. RTD sensor as reference for control, and 1 no. RTD sensors for indication only. Sensor break indication is provided and is displayed as "OPEN" against the process value.

The control action is a proportioning on-off type of control with a SSR (solid state relay) drive output.

The heater status is shown on the LED marked 'Heater'.

A pair of potential free contacts is provided and can be used to operate a solenoid valve for Air purge / Steam exhaust. The relay status is shown on the LED marked 'Purge'.

It has provision for sensing low water level with the provision of a level switch. At any time, the level switch activates, an audio alarm is sounded and the display shows "WATER LOW".

The data is date, time & the 4 channels temperature is logged every minute. When requested to print, at the end of the cycle, the data is dumped to the serial printer.

The OSWORLD Autoclave steam sterilizer produces a working pressure of 15 PSI (1.1 kg/cm^2) maximum attainable pressure is 25 PSI (1.7.kg/cm^2). Once autoclaving pressure is reached the control mechanism ensures precise control of conditions within chamber. A timer if installed helps provide selectable cycle soaking time. Precise temperature and time control ensures complete sterile media/glass ware/instruments. The lid and flange are of pressed stainless steel which enhances the construction of the autoclave. The chamber and cover are also made of stainless steel. As an additional safety measure a

spring loaded safety valve blows of steam in case of accidental pressure build up of more then the required pressure, ensuring total safety of operation.

7.0 REASON FOR QUALIFICATION:

New Equipment Come in Washing & Sterilization Area

.

8.0 SITE OF STUDY:

Washing & Sterilization Area.

9.0 FREQUENCY OF REQUALIFICATION :

- Vertical Autoclave should be validated once in a year ±1 month
- Whenever any major changes done in the load is taken place.
- After major maintenance or modification of existing equipment.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity.

10.1 Training Record of Validation Team:

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

10.2 Calibration of Test Instruments:

- Calibration of all the instruments used for qualification should be mentioned along with Calibration Certificates.

11.0 TESTS & CHECKS:

The autoclave is qualified by conducting for at least Three Consecutive Separate Successful Runs to Ensure that the results are consistent and meaningful.

Qualification cycle as per below table**:** Each Cycle NLT 30 min.

1. **Heat Distribution Study (Empty Chamber) (03 Cycles)**
2. **Heat penetration study. (Garment loaded chamber) (Minimum): (03 Cycles)**
3. **Heat penetration study. (Garment loaded chamber) (Maximum): (03 Cycles)**
4. **Heat penetration study. (Accessories load) (minimum): (03 Cycles)**
5. **Heat penetration study. (Accessories load) (Maximum): (03 Cycles)**
6. **Heat penetration study. (Mix load) (03 Cycles)**

Bio-challenge studies using Geobacillus Stearothermophilus spore ampoule (containing 10^6 or more spore) during the heat penetration studies.

Estimation of the F_0 value achieved by the cold and hot point location during the sterilization hold period at each temperature mapping probe at 121.4 °C for 20 minutes and 30 minutes.

The autoclave will be considered validated on successful completion of all the cycles.

11.1 HEAT DISTRIBUTION STUDY AT 121.4 °C FOR 30 MINUTES

Objective:

Objective of this test is to verify that the temperature uniformity throughout the chamber and to Locate the Hot & cold spot in empty Chamber.

- The sterilizer is capable of attaining a temperature of 121.4 °C during the sterilization hold period of 30 minutes with steam pressure of 15 psi.
- 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.
- The sensor having the slowest to heat is designated as the Cold Spot.
- The sensor having the fastest to heat is designated as the Hot Spot.

Procedure:

- Open the door of vertical autoclave and insert the 12 sensors through validation port into the chamber.
- Close the door of an Autoclave and connect the outputs of the 12 sensors to the Temperature Data logger.
- Set the temperature at 121.4°C and Sterilization hold time 30 minutes. Now start the cycle as per SOP.
- Simultaneously start the recording with data logger for each 10 Seconds and take printout at the end of the cycle switch off.
- At the end of the cycle Switch OFF the mains switch.
- When pressure becomes 15 psi, open the door with the help of safety gloves.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.

Acceptance Criteria

- There should be uniform distribution of heat in the sterilizer chamber during the sterilization hold period and the temperature at each temperature mapping probe should be within the range of 121.4 °C to 124 °C during the sterilization hold period.
- The interval of time between the attainment of the sterilization temperature in the hottest and coldest part of the chamber does not exceed 1 minute.

Table 1: Location of Sensors inside the chamber:

SENSOR No.	LOCATION IN THE CHAMBER
S-01	Chamber drain.
S-02	Lower basket (Bottom Side).
S-03	Lower basket (Middle Side).
S-04	Lower basket (Upper Side).
L-05	Hanging in middle of lower basket.
S-06	Upper basket (Middle Side).
S-07	Upper basket (Upper Side).
S-08	Upper basket (Bottom Side).
S-09	Hanging in middle of upper basket.
S-10	Middle of chamber
S-11	Middle of chamber
S-12	Upper basket Side

11.2 HEAT PENETRATION STUDY

Heat Penetration Studies in Cycle

- Anti Static Garment Load (Minimum and Maximum Load)
- Accessories Load (Minimum and Maximum Load)
- Mix Load

11.3 HEAT PENETRATION STUDY (GARMENT LOADED CHAMBER) (MINIMUM):

Objective: Objective of this test is 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 of 30 minutes with steam pressure of 15 lb/inch^2.
- If sterilization temperature (121.4°C) is not achieved throughout the cycle, load configuration or size of the load has to be reviewed and cycles to be repeated.
- 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.
- Cycle parameters:

  Set Temperature: 121.4^{0}C
  Overshoot Temperature: 124 ^{0}C
  Pressure : 15 psi

A) Load Details:

- Anti Static Garment : 8 Nos
- Mopping pad : 5 Nos
- IPA Bottle : 2 Nos
- Goggle : 8 Nos

Table 2: Location of Sensors and BI in the chamber

SENSOR No.	LOCATION IN THE CHAMBER
S-01	Chamber drain.
S-02	In the Garment at middle side
S-03	In the Garment at upper side
S-04	In the Garment at bottom of SS Containers
L-05	In the Garment at bottom of SS Containers
S-06	In the Middle of Mopping Pad
S-07	In the Garment at upper side of SS Container (C2)
S-08	In the Garment at Lower side
S-09	In the Middle of Goggle
S-10	In the Upper of Goggle
S-11	In the Upper of Mopping Pad
S-12	In the Lower of Mopping Pad

Procedure:

- Conduct the study with loaded chamber cycles with temperature probes and Biological Indicators.
- Transfer the load to autoclave sterilizer and connect the 12 sensors as per the Table No.02
- Connect the outputs of all the sensors to the data logger and close the door of sterilizer.
- Switch ON the MAINS of the control panel and set the parameters:

  Set Temperature : 121.4^0C
  Overshoot Temperature: 124 ^{0}C
  Pressure : 15 psi
  Hold Time : 30 minutes
- Now start the cycle as per SOP No. for Operating Instruction.
- Simultaneously start the recording with data logger for each 10 Seconds and take printout at the end of the cycle switch off.

- After the completion of cycle, open the door and remove BI, Chemical Indicators & sensors from load with the help of gloves.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Finally calculate the Lag period, F_0 value in each load.

Acceptance Criteria:

- There should be uniform distribution of temperature within the range of 121.4°C to 124 °C at each probe in sterilizer chamber during sterilization hold period.
- Each autoclaved Biological indicator should give '-ve' (Negative) results after the incubation.

11.4 HEAT PENETRATION STUDY AT 121.4 °C FOR 30 MINUTES FOR (GARMENT LOADED) MAXIMUM LOAD

Load Details:

- Anti Static Garment : 15 Nos
- Mopping pad : 10 Nos
- IPA Bottle : 5 Nos
- Goggle : 15 Nos

Table 3: Location of Sensors and BI in the chamber

SENSOR No.	LOCATION IN THE CHAMBER
S-01	Chamber drain.
S-02	In the Garment at middle side
S-03	In the Garment at upper side
S-04	In the Garment at bottom of SS Containers
L-05	In the Garment at bottom of SS Containers
S-06	In the Middle of Mopping Pad
S-07	In the Garment at upper side of SS Container (C2)
S-08	In the Garment at Lower side
S-09	In the Middle of Goggle
S-10	In the Upper of Goggle
S-11	In the Upper of Mopping Pad
S-12	In the Lower of Mopping Pad

Procedure:

- Conduct the study with loaded chamber cycles with temperature probes and Biological Indicators.
- Transfer the load to autoclave sterilizer and connect the 12 sensors as per the Table No.03.
- Connect the outputs of all the sensors to the data logger and close the door of sterilizer.
- Switch ON the MAINS of the control panel and set the parameters:

  Set Temperature : 121.4^0C
  Overshoot Temperature : 124 ^{0}C
  Pressure : 15 psi
- Now start the cycle as per SOP No. for Operating Instruction.
- Simultaneously start the recording with data logger for each 10 Seconds and take printout at the end of the cycle switch off.
- After the completion of cycle, open the door and remove BI, Chemical Indicators & sensors from load with the help of gloves.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure..
- Finally calculate the Lag period, F_0 value in each load.

Acceptance Criteria:

- There should be uniform distribution of temperature within the range of 121.4°C to 124 °C at each probe in sterilizer chamber during sterilization hold period.
- Each autoclaved Biological indicator should give '-ve' (Negative) results after the incubation.

11.5 HEAT PENETRATION STUDY AT 121.4 °C FOR 30 MINUTES FOR (ACCESSORIES) MINIMUM LOAD

Load details

Nylon Cloth	: 01 Nos.
Filter Cartridge	: 01 Nos
SS Mug 5 lt	: 01Nos.
SS Mug 2 lt	: 01 Nos.
SS Mug 1 lt	: 01 Nos.
Cone Filter	: 01 Nos
Mesh	: 01 Nos
Flexible hose Pipe	: 02 Nos..
TC Clamp with Gasket	: 10Nos

Table 4: Location of Sensors and BI in the chamber

SENSOR No.	LOCATION IN THE CHAMBER
S-01	Chamber drain.
S-02	Inside the SS Mug
S-03	Inside the SS Mug
S-04	Inside the SS Mug
L-05	Inside the Flexible hose pipe
S-06	Inside the Flexible hose pipe
S-07	Middle of The Chamber
S-08	Upper Side of Chamber
S-09	Upper Side of SS Mug
S-10	Upper Side of SS Mug
S-11	Bottom of The Chamber
S-12	Upper Side Of Flexible hose pipe

Procedure:

- Conduct the study with loaded chamber cycles with temperature probes and Biological Indicators.
- Transfer the load to autoclave sterilizer and connect the 12 sensors as per the Table No.04.
- Connect the outputs of all the sensors to the data logger and close the door of sterilizer.
- Switch ON the MAINS of the control panel and set the parameters:

  Set Temperature : 121.4^0C
  Overshoot Temperature : 124 ^{0}C
  Pressure : 15 psi
- Now start the cycle as per SOP No. for Operating Instruction.
- Simultaneously start the recording with data logger for each 10 Seconds and take printout at the end of the cycle switch off.
- After the completion of cycle, open the door and remove BI, Chemical Indicators & sensors from load with the help of gloves.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Finally calculate the Lag period, F_0 value in each load.

Acceptance Criteria:

- There should be uniform distribution of temperature within the range of 121.4°C to 124 °C at each probe in sterilizer chamber during sterilization hold period.
- Each autoclaved Biological indicator should give '-ve' (Negative) results after the incubation.

11.6 HEAT PENETRATION STUDY AT 121.4°C FOR 30 MINUTES FOR (ACCESSORIES) MAXIMUM LOAD

Load Details

Nylon Cloth	: 02 Nos.
Filter Cartridge	: 02 Nos
SS Mug 5 lt	: 02Nos.
SS Mug 2 lt	: 02 Nos.
SS Mug 1 lt	: 02 Nos.
Cone Filter	: 02 Nos
Mesh	: 02 Nos
Flexible hose Pipe	: 02 Nos..
TC Clamp with Gasket	: 20 Nos

Table 5: Location of Sensors and BI in the chamber

SENSOR No.	LOCATION IN THE CHAMBER
S-01	Chamber drain.
S-02	Inside the SS Mug
S-03	Inside the SS Mug
S-04	Inside the SS Mug
L-05	Inside the Flexible hose pipe
S-06	Inside the Flexible hose pipe
S-07	Middle of The Chamber
S-08	Upper Side of Chamber
S-09	Upper Side of SS Mug
S-10	Upper Side of SS Mug
S-11	Bottom of The Chamber
S-12	Upper Side Of Flexible hose pipe

Procedure:

- Conduct the study with loaded chamber cycles with temperature probes and Biological Indicators.
- Transfer the load to autoclave sterilizer and connect the 12 sensors as per the Table No.05.
- Connect the outputs of all the sensors to the data logger and close the door of sterilizer.
- Switch ON the MAINS of the control panel and set the parameters:
- Set Temperature : 121.4^0C
- Overshoot Temperature : 124 ^{0}C
- Pressure : 15 psi

- Now start the cycle as per SOP No. for Operating Instruction.
- Simultaneously start the recording with data logger for each 10 Seconds and take printout at the end of the cycle switch off.
- After the completion of cycle, open the door and remove BI, Chemical Indicators & sensors from load with the help of gloves.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Finally calculate the Lag period, F_0 value in each load.

Acceptance Criteria:

- There should be uniform distribution of temperature within the range of 121.4°C to 124 °C at each probe in sterilizer chamber during sterilization hold period.
- Each autoclaved Biological indicator should give '-ve' (Negative) results after the incubation.

11.7 HEAT PENETRATION STUDY AT 121.4°C FOR 30 MINUTES FOR MIX LOAD

Load Details

Nylon Cloth	: 02 Nos.
Filter Cartridge (5 Inch)	: 01 Nos
Filter Cartridge (10 Inch)	: 01 Nos
IPA Bottle	: 02 Nos.
Goggle	: 02 Nos.
SS Mug 2 lt	: 02 Nos.
Flexible hose Pipe	: 02Nos..
Anti Static Garment	: 02 Nos

Table 5: Location of Sensors and BI in the chamber

SENSOR No.	LOCATION IN THE CHAMBER
S-01	Chamber drain.
S-02	Inside the SS Mug
S-03	Inside the SS Mug
S-04	Inside the SS Mug
L-05	Inside the Flexible hose pipe
S-06	Inside the Flexible hose pipe
S-07	Middle of TC Clamp with Gasket
S-08	Upper Side of Chamber
S-09	Middle Of Garment
S-10	Middle of Nylon Cloth
S-11	Inside of IPA bottle
S-12	Middle of the Chamber

Procedure:

- Conduct the study with loaded chamber cycles with temperature probes and Biological Indicators.
- Transfer the load to autoclave sterilizer and connect the 12 sensors as per the Table No.05.
- Connect the outputs of all the sensors to the data logger and close the door of sterilizer.
- Switch ON the MAINS of the control panel and set the parameters:
- Set Temperature : 121.4^0C
- Overshoot Temperature : 124 ^{0}C
- Pressure : 15 psi
- Now start the cycle as per SOP No. for Operating Instruction.
- Simultaneously start the recording with data logger for each 10 Seconds and take printout at the end of the cycle switch off.
- After the completion of cycle, open the door and remove BI, Chemical Indicators & sensors from load with the help of gloves.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Finally calculate the Lag period, F_0 value in each load.

Acceptance Criteria:

- There should be uniform distribution of temperature within the range of 121.4°C to 124 °C at each probe in sterilizer chamber during sterilization hold period.

  Each autoclaved Biological indicator should give '-ve' (Negative) results after the incubation

11.8 F_0 CALCULATION

11.8.1 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 vertical Autoclave.
- 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.
- When pressure becomes 0.030 psi, open the door of 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.

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.

11.8.2 ESTIMATION OF F_0 VALUE:

A) Numerical F_0 Value:

The actual observations obtained during the heat penetration studies at different temperature sensing locations are complied in the table and the observed temperature shell be subjected for calculation of F_0 values at that particular location. The lethality factor calculations are done by using the following formula and the computed (during the sterilization period) are given in the following table.

$F_0 = dt \sum 10^{(T-121)/Z}$ …… (a)

$F_0 = dt \sum$ (Sum of lethality factors).

Where,

dt = time interval between successive temperature measurements.

T = observed temperature at that particular time (as per the actual temperatures recorded).

Z = change in the heat resistance of ***Geobacillus stearothermophilus*** spores as temperature is changed (AS Per Party COA).

B) F_0 Value for Biological Indicators:

The biological F_0 value for biological indicator strip exposed during the sterilization can be calculated as follows.

$F_0 = D_{121}$ (log A – log B)…….. (b)

Where,

D_{121}	D value of the biological indicator at 121°C.
A	Experimental Biological indicator concentration or spore population.
B	Desired level of sterility (SAL- 10^{-6}).

C) Desired Spore Log Reduction:

Calculate the desired reduction in spore population by using the formula-

$SLR_{desired}$ = log A- log $SAL_{desired}$ ……..(c)

Where,

A = Experimental population of Biological Indicator at 121 °C.

$SAL_{desired}$ = Desired level of sterility (10^{-6}).

D) Actual Spore Log Reduction:

Calculate actual reduction in spore population by using the formula-

$SLR_{Actual} = F_0 / D_{121}$……. (d)

Where,

F_0 = Minimum calculated F_0 value.

D_{121}= D value of Biological Indicator.

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	TEST & CHECK	EXECUTION YES/ NO	VERIFIED BY QA SIGN/DATE
1.	Verification of Document		
1.2	Training Record of Person involve Performance Qualification Activity		
1.3	Calibration Certificate of Test Instrument.		
1.4	Pre Calibration of Test Instrument		
2.	Verification of Heat Distribution Study (3 Cycle)		
3.	Verification of Heat Penetration Study for Loaded		
3.1	Heat Penetration Study for Garment Minimum Load (3 Cycle)		
3.2	Heat Penetration Study for Garment Maximum Load (3 Cycle)		
3.3	Heat Penetration Study for Accessories Minimum Load (3 Cycle)		
3.4	Heat Penetration Study for Accessories Maximum Load (3 Cycle)		
3.5	Heat Penetration Study for Mix Load (3 Cycle)		
4.	Post Calibration of Test Instrument		

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).
- 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.

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:

BI	:	Biological Indicator
cGMP	:	Current Good Manufacturing Practices
CI	:	Chemical Indicator
cm	:	Centimetre
HTM	:	Health Technical Memorandum
ID.	:	Identification
IQ	:	Installation Qualification
kg	:	Kilogram
L	:	Location
NLT	:	Not Less Than
Nos.	:	Numbers
OQ	:	Operational Qualification
PDA	:	Parenteral Drug Association
PPQ	:	Performance Qualification Protocol
PQ	:	Performance Qualification
RTD	:	Resistance Temperature Detector
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
-ve	:	Negative
VLA	:	Vertical Autoclave
WHO	:	World Health Organization