



PHARMA DEVILS

**PERFORMANCE
QUALIFICATION REPORT
FOR
VERTICAL AUTOCLAVE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
VERTICAL AUTOCLAVE**

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SUPERSEDED PROTOCOL No.	NIL



**PERFORMANCE
QUALIFICATION REPORT
FOR
VERTICAL AUTOCLAVE**

PROTOCOL No.:

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PROTOCOL No.:

1.0 REPORT PRE -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)			



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2.0 OBJECTIVE:

- This Performance Qualification Report is designed to establish & provided the documentary evidence, to assure that the Vertical Autoclave, supplied by Oswarld is suitable for sterilizing the loads 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 Performance Qualification Report 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:

- The Performance Qualification Report covers all aspects of Performance qualification for the Vertical Autoclave for Cleaned Equipment, accessories and machine parts in the Washing & Sterilization Area Section.



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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, Review, Approval and Compilation of the Performance Qualification Report.• Training to validation team for qualification of vertical Autoclave system.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification Activity.• Post Approval of Performance Qualification Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post Approval of Performance Qualification Report after Execution.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Performance Qualification Report.• Co-ordination, Execution and technical support in Qualification activity.• Calibration of Process Instruments.• Responsible for Trouble shooting (if occurs during execution).• Post Approval of Performance Qualification Report after Execution.
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	Vertical Autoclave
Equipment	
Manufacturer's Name	Oswarld
Model	
S.No.	
Capacity	175 Ltr.
Supplier's Name	Oswarld
Location of Installation	Washing & Sterilization Area



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6.0 PRE QUALIFICATION REQUIRMENTS:

6.1 Training Record of Validation Team:

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

6.2 Calibration of Test Instruments:

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

S.No.	Name of Test Instrument	Date of Last Calibration	Next Due on	Status	Availability of Calibration Certificate	Verified By (QA) Sign/Date
1.						
2.						
3.						
4.						
5.						

Inference:

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Reviewed By:
(Manager QA)
(Sign & Date)



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PROTOCOL No.:

7.0 TEST AND CHECKS :

7.1 HEAT DISTRIBUTION STUDY AT 121.4 °C FOR 30 MINUTES :

Cycle Parameters	Cycle 1	Cycle 2	Cycle 3
Date			
Cycle Start Time			
Sterilization Hold Start Time			
Sterilization Hold completion Time			
Total Hold Time (minutes)			
Cycle completion Time			
Cycle completion Date			
Cold Spot (Sensor Location)			
Hot Spot (Sensor Location)			

**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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PROTOCOL No.:

7.2 HEAT PENETRATION STUDIES AT 121.1°C FOR 30 MINUTES (GARMENT LOAD) FOR MINIMUM LOAD

Cycle Parameters	Cycle 1	Cycle 2	Cycle 3
Date			
Cycle Start Time			
Sterilization Hold Start Time			
Sterilization Hold completion Time			
Total Hold Time (minutes)			
Cycle completion Time			
Cycle completion date			
Cold Spot (Sensor Location)			
Hot Spot (Sensor Location)			

**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
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FOR
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PROTOCOL No.:

7.2.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-01

Status of Chemical Indicator Strip

S.No.	Observation	S.No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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**PERFORMANCE
QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.2.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-02

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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**PERFORMANCE
QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.2.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-03

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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**PERFORMANCE
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FOR
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PROTOCOL No.:

7.2.4 F₀ CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z} \text{ _____}$$

F₀ =

Where,

- dt : Time interval between successive temperature measurements (in min).
- 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 mentioned in COA).

(b) F₀ Value for Biological Indicators:

The biological F₀ value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B) \text{ _____}$$

F₀ =

Where,

- D₁₂₁ : D value of the biological indicator at 121⁰C
- 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-

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}} \text{ _____}$$

SLR_{desired} =

Where,

- A : Experimental population of Biological Indicator
- SLR_{desired} : Desired level of sterility (10⁻⁶)

(d) Actual Spore log reduction

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121} \text{ _____}$$

SLR_{Actual} =

Where,

- F₀ : Minimum Calculated F₀ value
- D₁₂₁ : D value of the Biological Indicator at 121⁰C



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PROTOCOL No.:

7.2.6 F₀ CALCULATION:

CYCLE -02

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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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PROTOCOL No.:

**7.3 HEAT PENETRATION STUDIES AT 121.4°C FOR 30 MINUTES (GARMENT LOAD) FOR
MAXIMUM LOAD**

Cycle Parameters	Cycle 1	Cycle 2	Cycle 3
Date			
Cycle Start Time			
Sterilization Hold Start Time			
Sterilization Hold completion Time			
Total Hold Time (minutes)			
Cycle completion Time			
Cycle completion Date			
Cold Spot (Sensor Location)			
Hot Spot (Sensor Location)			

**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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QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.3.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-01

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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PROTOCOL No.:

7.3.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-02

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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PROTOCOL No.:

7.3.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-03

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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PROTOCOL No.:

7.3.4 F₀ CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z} \text{ _____}$$

F₀ =

Where,

dt : Time interval between successive temperature measurements (in min).

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 (10⁰C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

The biological F₀ value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B) \text{ _____}$$

F₀ =

Where,

D₁₂₁ : D value of the biological indicator at 121⁰C

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-

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}} \text{ _____}$$

SLR_{desired} =

Where,

A : Experimental population of Biological Indicator

SLR_{desired} : Desired level of sterility (10⁻⁶)

(d) Actual Spore log reduction

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121} \text{ _____}$$

SLR_{Actual} =

Where,

F₀ : Minimum Calculated F₀ value

D₁₂₁ : D value of the Biological Indicator at 121⁰C



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PROTOCOL No.:

7.3.6 F₀ CALCULATION:

CYCLE -02

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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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PROTOCOL No.:

7.3.7 F₀ CALCULATION:

CYCLE -03

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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
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FOR
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PROTOCOL No.:

**7.4 HEAT PENETRATION STUDY AT 121.4 °C FOR 30 MINUTES FOR (ACCESSORIES)
MINIMUM LOAD:**

Cycle Parameters	Cycle 1	Cycle 2	Cycle 3
Date			
Cycle Start Time			
Sterilization Hold Start Time			
Sterilization Hold completion Time			
Total Hold Time (minutes)			
Cycle completion Time			
Cycle completion Date			
Cold Spot (Sensor Location)			
Hot Spot (Sensor Location)			

**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
VERTICAL AUTOCLAVE**

PROTOCOL No.:

7.4.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-01

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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**PERFORMANCE
QUALIFICATION REPORT
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PROTOCOL No.:

7.4.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-02

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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**PERFORMANCE
QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.4.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-03

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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FOR
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PROTOCOL No.:

7.4.4 F₀ CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z} \text{ _____}$$

F₀ =

Where,

dt : Time interval between successive temperature measurements (in min).

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 (10⁰C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

The biological F₀ value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B) \text{ _____}$$

F₀ =

Where,

D₁₂₁ : D value of the biological indicator at 121⁰C

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-

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}} \text{ _____}$$

SLR_{desired} =

Where,

A : Experimental population of Biological Indicator

SLR_{desired} : Desired level of sterility (10⁻⁶)

(d) Actual Spore log reduction

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121} \text{ _____}$$

SLR_{Actual} =

Where,

F₀ : Minimum Calculated F₀ value

D₁₂₁ : D value of the Biological Indicator at 121⁰C



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7.4.5 F₀ CALCULATION:

CYCLE -01

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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
VERTICAL AUTOCLAVE**

PROTOCOL No.:

7.4.6 F₀ CALCULATION:

CYCLE -02

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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
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PROTOCOL No.:

**7.5 HEAT PENETRATION STUDY AT 121.4 °C FOR 30 MINUTES FOR (ACCESSORIES)
MAXIMUM LOAD:**

Cycle Parameters	Cycle 1	Cycle 2	Cycle 3
Date			
Cycle Start Time			
Sterilization Hold Start Time			
Sterilization Hold completion Time			
Total Hold Time (minutes)			
Cycle completion Time			
Cycle completion Date			
Cold Spot (Sensor Location)			
Hot Spot (Sensor Location)			

**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
VERTICAL AUTOCLAVE**

PROTOCOL No.:

7.5.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-01

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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PROTOCOL No.:

7.5.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-02

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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**PERFORMANCE
QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.5.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-03

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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FOR
VERTICAL AUTOCLAVE

PROTOCOL No.:

7.5.4 F₀ CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z} \text{ _____}$$

F₀ =

Where,

dt : Time interval between successive temperature measurements (in min).

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 (10⁰C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

The biological F₀ value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B) \text{ _____}$$

F₀ =

Where,

D₁₂₁ : D value of the biological indicator at 121⁰C

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-

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}} \text{ _____}$$

SLR_{desired} =

Where,

A : Experimental population of Biological Indicator

SLR_{desired} : Desired level of sterility (10⁻⁶)

(d) Actual Spore log reduction

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121} \text{ _____}$$

SLR_{Actual} =

Where,

F₀ : Minimum Calculated F₀ value

D₁₂₁ : D value of the Biological Indicator at 121⁰C



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FOR
VERTICAL AUTOCLAVE**

PROTOCOL No.:

7.5.5 F₀ CALCULATION:

CYCLE -01

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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
VERTICAL AUTOCLAVE**

PROTOCOL No.:

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

Cycle Parameters	Cycle 1	Cycle 2	Cycle 3
Date			
Cycle Start Time			
Sterilization Hold Start Time			
Sterilization Hold completion Time			
Total Hold Time (minutes)			
Cycle completion Time			
Cycle completion Date			
Cold Spot (Sensor Location)			
Hot Spot (Sensor Location)			

**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
VERTICAL AUTOCLAVE**

PROTOCOL No.:

7.6.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-01

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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VERTICAL AUTOCLAVE**

PROTOCOL No.:

7.6.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-02

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



PHARMA DEVILS

**PERFORMANCE
QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.6.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-03

Status of Chemical Indicator Strip

S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

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



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PROTOCOL No.:

7.6.4 F₀ CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

$$F_0 = dt \sum 10^{(T-121)/Z} \text{ _____}$$

F₀ =

Where,

dt : Time interval between successive temperature measurements (in min).

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 (10⁰C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

The biological F₀ value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B) \text{ _____}$$

F₀ =

Where,

D₁₂₁ : D value of the biological indicator at 121⁰C

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-

$$SLR_{\text{desired}} = \log A - \log SAL_{\text{desired}} \text{ _____}$$

SLR_{desired} =

Where,

A : Experimental population of Biological Indicator

SLR_{desired} : Desired level of sterility (10⁻⁶)

(d) Actual Spore log reduction

Calculate actual reduction in spore population by using the formula

$$SLR_{\text{Actual}} = F_0 / D_{121} \text{ _____}$$

SLR_{Actual} =

Where,

F₀ : Minimum Calculated F₀ value

D₁₂₁ : D value of the Biological Indicator at 121⁰C



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7.6.6 F₀ CALCULATION:

CYCLE -02

Probe No	Sterilizing Temperature (°c)		F ₀ Value		Spore Log Reduction		Biological Indicator Status
	Minimum	Maximum	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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PROTOCOL No.:

7.6.7 F₀ CALCULATION:

CYCLE -03

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

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

**Verified By
(Quality Assurance)
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.

S.No	TEST & CHECK	EXECUTION YES/ NO	VERIFIED BY (QUALITY ASSURANCE) SIGN/DATE
1.	Verification of Document		
1.1	SOP are Effective		
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.	Pre & Post Calibration Certificate of Sensor		

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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9.0 DOCUMENTS TO BE ATTACHED:

- Biological Indicator Incubation Report.
- Calibration Certificates of Sensors of Data Logger.
- Pre & Post Calibration Certificate of Sensor
- Any Other Relevant Document

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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16.0 ABBREVIATIONS:

+ve	:	Positive
BI	:	Biological Indicator
cGMP	:	Current Good Manufacturing Practices
CI	:	Chemical Indicator
HTM	:	Health Technical Memorandum
ID	:	Identification
L	:	Location
Mfg.	:	Manufacturing
Nos.	:	Numbers
PQ	:	Performance Qualification
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
SS	:	Stainless Steel
Temp.	:	Temperature
-ve	:	Negative
VLA	:	Vertical Autoclave



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17.0 REPORT POST -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)			