

PROTOCOL No.:

PERFORMANCE QUALIFICATION REPORT FOR VERTICAL AUTOCLAVE

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SUPERSEDED PROTOCOL No.	NIL



PROTOCOL No.:

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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)			



PROTOCOL No.:

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.



PROTOCOL No.:

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	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	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	Analytical Support (Microbiological Testing/Analysis).
Engineering	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)	Performance of Qualification activity as per protocol



PROTOCOL No.:

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



Inference:

PERFORMANCE QUALIFICATION REPORT FOR VERTICAL AUTOCLAVE

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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.						

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



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7.0 TEST AND CHECKS	7.0	J IE	21	A.	NU	, C	ш	שע	$\mathbf{N}_{\mathbf{C}}$) ;
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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:	
	Reviewed By (Manager QA) Sign/Date:



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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 B (Quality A Sign/Date	-			
Inference:						

Reviewed By (Manager QA)

Sign/Date:



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7.2.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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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ΓN	. , ,	``		, ,	NO.

7.2.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

	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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7.2.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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 Ass	urance)
Sign/Date	



PROTOCOL No.:

7.2.4 Fo CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

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

 $F_0 =$

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

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

 $F_0=$

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

 $SLR_{desired} =$

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 $Actual = F_0 / D_{121}$

SLR Actual = Where,

F₀ : Minimum Calculated F_{0 value}

 D_{121} : D value of the Biological Indicator at 121° C



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7.2.5 Fo CALCULATION SUMMRY:

Duck a No	Ster Tempe	rilizing rature (°c)	F _o V	alue	Spore Log Reduction		Biological	
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status	
Checked E (Production Sign/Date:	By on)					Verified By (Quality As Sign/Date	surance)	
Inference:								
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Probe No		rilizing rature (°c)	F _o V	alue	Spore Log Reduction		Biological
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked F (Production Sign/Date:						Verified By (Quality As Sign/Date	
Inference:							
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7.2.7 Fo C.	ALCUL	LATION:
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D . I . N		rilizing rature (°c)	F _o V	alue	Spore Log	g Reduction	Biological	
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status	
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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)			
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Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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7.3.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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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7.3.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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	
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Sign/Date	



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7.3.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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	 			



PROTOCOL No.:

7.3.4 Fo CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

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

 $F_0 =$

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 (10°C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

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

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

 $F_0=$

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 _____

 $SLR_{desired} =$

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 $Actual = F_0 / D_{121}$

SLR Actual = Where,

F₀ : Minimum Calculated F_{0 value}

 D_{121} : D value of the Biological Indicator at 121° C



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7.3.5	Fo	CAL	CUL	AT	ON:
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Sterilizing

Duobo No		rilizing rature (°c)	F _o V	Value Spore Log Reduction		Biological	
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked By (Production) Sign/Date:						Verified By (Quality Ass Sign/Date	surance)
Inference:							
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PERFORMANCE QUALIFICATION REPORT FOR VERTICAL AUTOCLAVE

Spore Log Reduction

Fo Value

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7.3.6 Fo CALCULATION:

Sterilizing

D1 N	Temperature (°c)		F _o V	alue	Spore Log	Reduction	Biological		
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status		
Checked F	$\mathbf{B}\mathbf{y}$					Verified By			
(Production Sign/Date:	(Production) Sign/Date:					(Quality As Sign/Date.	surance) 		
						8			
Inference:									
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7.3.7 F ₀ CALCULATION	7.3.7	Fo	CAL	CUL	AT	ION
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Ducha Ma	Probe No Sterilizing Temperature (°c) Minimum Maximum		F _o V	alue	Spore Log	Reduction	Biological	
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status	
Checked B (Production Sign/Date:	By n)					Verified By (Quality As Sign/Date	surance)	
Inference:								
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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:	
	Reviewed By
	(Manager QA) Sign/Date:



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7.4.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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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7.4.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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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7.4.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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	



PROTOCOL No.:

7.4.4 Fo CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

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

 $F_0 =$

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 (10°C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

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

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

 $F_0=$

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 _____

 $SLR_{desired} =$

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 $Actual = F_0 / D_{121}$

SLR Actual = Where,

F₀ : Minimum Calculated F_{0 value}

 D_{121} : D value of the Biological Indicator at 121° C



PERFORMANCE QUALIFICATION REPORT FOR VERTICAL AUTOCLAVE

Spore Log Reduction

Fo Value

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7.4.5 Fo CALCULATION)N:
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Sterilizing

D1 N	Tempe	rature (°c)	F _o V	alue	Spore Log Reduction		Biological	
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status	
Checked F	$\mathbf{B}\mathbf{y}$					Verified By		
(Production Sign/Date:	on) :					(Quality As Sign/Date.	surance) 	
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Inference:								
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						(Manager (QA)	
						Sign/Date:		



Probe No

PERFORMANCE QUALIFICATION REPORT FOR VERTICAL AUTOCLAVE

Fo Value

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Biological

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Sterilizing

Temperature (°c)

CYCLE -02

Spore Log Reduction

	Minimum	Maximum	Numerical	BI	Desired	Actual	indicator Status
Checked E (Production Sign/Date:	By on)					Verified By (Quality Ass Sign/Date	surance)
Inference:							
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Sterilizing

Duch a Ma		rilizing rature (°c)	F _o V	alue	Spore Log	Reduction	Biological
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked E (Production Sign/Date:	8y on)					Verified By (Quality As Sign/Date.	surance)
Inference:							
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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	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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7.5.1 OBSERVATION REPORT OF CHEMICAL INDICATOR:

	Status of Chamina	l Indiant	C4
G N	Status of Chemica		
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

Verified By	
(Quality Assurance)	
Sign/Date	



PR	$\Gamma \Gamma$	n	CO	Τ.	No.
ΓN	. , ,	``		, ,	NO.

7.5.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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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7.5.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

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	



PROTOCOL No.:

7.5.4 Fo CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

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

 $F_0 =$

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 (10°C or as mentioned in COA).

(b) F_0 Value for Biological Indicators:

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

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

 $F_0=$

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

 $SLR_{desired} =$

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 $Actual = F_0 / D_{121}$

SLR Actual = Where,

F₀ : Minimum Calculated F_{0 value}

 D_{121} : D value of the Biological Indicator at 121° C



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7.5.5 Fo CALCULATION:

Duck - No	Sterilizing Temperature (°c)		F _o Value		Spore Log Reduction		Biological
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked F (Production Sign/Date:	By on)					Verified By (Quality As Sign/Date	surance)
Inference:							
•••••					• • • • • • • • • • • • • • • • • • • •		
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						Reviewed B (Manager (Sign/Date:	



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7.5.6 Fo CALCULATION	N	:
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Sterilizing

Duck a M-	Sterilizing Temperature (°c)		F _o Value		Spore Log Reduction		Biological	
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status	
Checked B (Production Sign/Date:	n)					Verified By (Quality As Sign/Date	surance)	
Inference:								
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						(Manager (QA)	
						Sign/Date:		



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7.5.7 Fo CALCULATION:

Duoho No	Sterilizing Temperature (°c)		Fo Value		Spore Log	Reduction	Biological
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked B (Production Sign/Date:	n)					Verified By (Quality As Sign/Date	surance)
Inference:							
•••••	• • • • • • • • • • • • • • • • • • • •		••••••	•••••			
						Reviewed B (Manager Q Sign/Date: .	



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7.6 HEAT PENETRATION STUDY AT 121.4°C FOR 30 MINUTES FOR MIX LOAD Cycle Parameters Cycle 1 Cycle 2 Cycle 3								
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)								
Production) Sign/Date:			Assurance)					
Sign/Date:								
ign/Date:								
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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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7.6.2 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-02

	Status of Chemica	l 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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7.6.3 OBSERVATION REPORT OF CHEMICAL INDICATOR:

CYCLE No.-03

	Status of Chemica	l Indicator	Strip
S. No.	Observation	S. No.	Observation
1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

Verified By	
(Quality Assu	rance)
Sign/Date	



PROTOCOL No.:

7.6.4 Fo CALCULATION

(a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

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

 $F_0 =$

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 (10°C or as mentioned in COA).

(b) F₀ Value for Biological Indicators:

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

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

 $F_0=$

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 _____

 $SLR_{desired} =$

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 $Actual = F_0 / D_{121}$

SLR Actual = Where,

F₀ : Minimum Calculated F_{0 value}

 D_{121} : D value of the Biological Indicator at 121^{0} C



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7.6.5 F_O CALCULATION:

Sterilizing

Probe No	Temperature (°c) Minimum Maximum		F _o Value		Spore Log	Reduction	Biological
Frode No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked B (Production Sign/Date:	n)					Verified By (Quality As: Sign/Date	surance)
Inference:							
•••••			••••••	•••••	••••••		
						Reviewed B (Manager Q Sign/Date: .	y 2A)



P	D	N	т	n	\mathbf{C}	N	T	N	$\mathbf{\Lambda}$	•
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7.6.6 Fo CALCULA	TION:
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Sterilizing

Probe No	Tempe	rature (°c)	I o	aiuc	Spore Lug	Keduction	Biological	
1 Tube No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status	
Checked E (Production Sign/Date:	n)					Verified By (Quality As Sign/Date	surance)	
Inference:								
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						Reviewed B	V	
						(Manager (QA)	
						Sign/Date:		



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7.6.7 Fo CALCULATION:

Sterilizing

Ducho No	Temperature (°c)		F _o Value		Spore Log	Reduction	Biological
Probe No	Minimum	Maximum	Numerical	BI	Desired	Actual	Indicator Status
Checked By (Production) Sign/Date: Verified By (Quality Assurance) Sign/Date					surance)		
Inference:							
•••••	• • • • • • • • • • • • • • • • • • • •	••••••		••••••	••••••	•••••	
						Reviewed B (Manager Q Sign/Date: .	y 2A)



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CHECKLIST OF ALL TESTS & CHECKS: 8.0

·	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						
Inferen	Inference:						

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:
11.0	DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:
12.0	CHANGE CONTROL, IF ANY:
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):



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14.0	CONCLUSION:
15.0	RECOMMENDATION:



PROTOCOL No.:

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)			