



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

**PERFORMANCE QUALIFICATION
REPORT
FOR
CIP-SIP SYSTEM**

EQUIPMENT ID No.	
LOCATION	LVP LINE
DATE OF QUALIFICATION	
SUPERSEDED REPORT No.	NIL



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

2.0 OBJECTIVE:

The objective of this validation report is to establish documented evidence that the CIP-SIP System is suitable for cleaning and sterilization of the manufacturing vessels & Holding vessels along with the associated product line with filter housings and filters can repeatedly and reproducibly be able to sterilize effectively the subjected system within the established acceptance criteria limits.

3.0 SCOPE:

The scope of this particular validation report is applicable to the CIP-SIP of manufacturing vessels and Holding vessels.

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, authorization and Compilation of Performance qualification Reports• To provide analytical support for validation activity.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing / Analysis)
Production	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance qualification Activity.
Engineering	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Validation Activity.• Responsible for Trouble shooting during execution (If Occurs).



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

5.0 EQUIPMENT DETAILS:

ID. Number
Equipment Name	SS Jacketed Manufacturing vessel	SS Jacketed Holding Vessel
Capacity	4000 Ltr.	4000 Ltr.
Gross Capacity	4805 Ltr.	4805 Ltr.
Manufacturer's Name		
S.No		
Model	cGMP Model.	cGMP Model.
Supplier's Name		
Location of Installation	Manufacturing Area	Filtration Area

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Verification of Documents:

S.No.	DOCUMENT NAME	COMPLETED (YES/NO)	CHECKED BY (QA) SIGN/DATE
1.	SOP for operation & Cleaning of CIP System		
2.	SOP for Preventive Maintenance CIP System		
3.	SOP for operation & Cleaning of SIP System		
4.	SOP for Preventive Maintenance SIP System		

Inference:

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



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.0 TESTS AND CHECKS:

7.1 CLEAN IN PLACE:

7.1.1 TEST FOR EFFICIENCY OF WASHING CYCLE FOR MANUFACTURING TANK (4000 Ltr.) & CONNECTED LOOP:

Date of Test		Equipment Name	
Name of Test		Equipment ID	

CIP Cycle with 15% NaOH

Parameter	Result			Acceptance criteria
	Cycle-I	Cycle-II	Cycle-III	
pH				5.0 to 7.0
Conductivity				NMT 1.3 μ s

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 CIP-SIP

7.1.2 TEST FOR EFFICIENCY OF WASHING CYCLE FOR HOLDING TANK (4000 Ltr.) & CONNECTED LOOP:

Date of Test		Equipment Name	
Name of Test		Equipment ID	

CIP Cycle with 15% NaOH

Parameter	Result			Acceptance criteria
	Cycle-I	Cycle-II	Cycle-III	
pH				5.0 to 7.0
Conductivity				NMT 1.3 μ s

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 CIP-SIP

7.2 STERILIZATION IN PLACE

7.2.1 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (4000 Ltr.) & CONNECTED LOOP: Cycle-I

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle		Heat Distribution Study	
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Cycle-01
Purging time	120 Second	
Sterilization Pressure	2.00 Bar	
Pressure Dead Band	0.30 bar	
Sterilization Temperature	121.5°C	
Heating on Temperature	122.5°C	
Heating off Temperature	123.5 °C	
Sterilization Hold Time	30 Min	
Sterilization Fail Temperature	119.0°C	
Overshoot Temperature	130.0°C	
Cooling Temperature	90.0°C	
Print Interval	60 Seconds	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.2 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-I
	Internal Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Total Hold time	

7.2.3 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-I
	External Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Cold Spot Location	
Cold Spot Sensor No.	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.4 F₀ CALCULATION

(a) (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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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.5 OBSERVATIONS:

Cycle-I

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

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

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

Inference:

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



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

**7.2.6 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (4000 Ltr.) &
CONNECTED LOOP: Cycle-II**

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle		Heat Distribution Study	
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Cycle-02
Purging time	120 Second	
Sterilization Pressure	2.00 Bar	
Pressure Dead Band	0.30 bar	
Sterilization Temperature	121.5°C	
Heating on Temperature	122.5°C	
Heating off Temperature	123.5 °C	
Sterilization Hold Time	30 Min	
Sterilization Fail Temperature	119.0°C	
Overshoot Temperature	130.0°C	
Cooling Temperature	90.0°C	
Print Interval	60 Seconds	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.7 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-II
	Internal Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Total Hold time	

7.2.8 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-II
	External Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Cold Spot Location	
Cold Spot Sensor No.	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.9 F₀ CALCULATION

(a) (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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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.10 OBSERVATIONS:

Cycle-II

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

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

**7.2.11 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (4000 Ltr.) &
CONNECTED LOOP: Cycle-III**

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle		Heat Distribution Study	
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Cycle-03
Purging time	120 Second	
Sterilization Pressure	2.00 Bar	
Pressure Dead Band	0.30 bar	
Sterilization Temperature	121.5°C	
Heating on Temperature	122.5°C	
Heating off Temperature	123.5 °C	
Sterilization Hold Time	30 Min	
Sterilization Fail Temperature	119.0°C	
Overshoot Temperature	130.0°C	
Cooling Temperature	90.0°C	
Print Interval	60 Seconds	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.12 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-III
	Internal Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Total Hold time	

7.2.13 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-III
	External Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Cold Spot Location	
Cold Spot Sensor No.	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.14 F₀ CALCULATION

(a) (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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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.15 OBSERVATIONS:

Cycle-III

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

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.16 HEAT DISTRIBUTION STUDY FOR HOLDING TANK (4000 Ltr.) & CONNECTED LOOP

Cycle-I:

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle	Heat Distribution Study		
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Cycle-01
Purging time	120 Second	
Sterilization Pressure	2.00 Bar	
Pressure Dead Band	0.30 bar	
Sterilization Temperature	121.5°C	
Heating on Temperature	122.5°C	
Heating off Temperature	123.5 °C	
Sterilization Hold Time	30 Min	
Sterilization Fail Temperature	119.0°C	
Overshoot Temperature	130.0°C	
Cooling Temperature	90.0°C	
Print Interval	60 Seconds	

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 CIP-SIP

7.2.17 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-I
	Internal Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Total Hold time	

7.2.18 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-I
	External Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Cold Spot Location	
Cold Spot Sensor No.	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.19 F₀ CALCULATION

(a) (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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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.20 OBSERVATIONS:

Cycle-I:

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

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

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Reviewed By
(Manager QA)
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.21 HEAT DISTRIBUTION STUDY FOR HOLDING TANK (4000 Ltr.) & CONNECTED LOOP:

Cycle-II

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle		Heat Distribution Study	
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Cycle-02
Purging time	120 Second	
Sterilization Pressure	2.00 Bar	
Pressure Dead Band	0.30 bar	
Sterilization Temperature	121.5°C	
Heating on Temperature	122.5°C	
Heating off Temperature	123.5 °C	
Sterilization Hold Time	30 Min	
Sterilization Fail Temperature	119.0°C	
Overshoot Temperature	130.0°C	
Cooling Temperature	90.0°C	
Print Interval	60 Seconds	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.22 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-II
	Internal Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Total Hold time	

7.2.23 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-II
	External Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Cold Spot Location	
Cold Spot Sensor No.	

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.24 F₀ CALCULATION

(a) (a) Numerical F₀ Value:

Calculate numerical F₀ value for below given formula.

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

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.

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

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-

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

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

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

SLR_{Actual} =

Where,

F₀ : Minimum Calculated F₀ value

D₁₂₁ : D value of the Biological Indicator at 121⁰C



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

7.2.25 OBSERVATIONS:

Cycle-II:

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

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



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7.2.26 HEAT DISTRIBUTION STUDY FOR HOLDING TANK (4000 Ltr.) & CONNECTED LOOP:

Cycle-III

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle		Heat Distribution Study	
Date of test		Equipment Make	
Equipment Name		Equipment ID	
Capacity of vessel		Equipment Location	

Set Parameters:	Acceptance Criteria	Cycle-03
Purging time	120 Second	
Sterilization Pressure	2.00 Bar	
Pressure Dead Band	0.30 bar	
Sterilization Temperature	121.5°C	
Heating on Temperature	122.5°C	
Heating off Temperature	123.5 °C	
Sterilization Hold Time	30 Min	
Sterilization Fail Temperature	119.0°C	
Overshoot Temperature	130.0°C	
Cooling Temperature	90.0°C	
Print Interval	60 Seconds	

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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7.2.27 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-III
	Internal Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Total Hold time	

7.2.28 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-III
	External Sensor
Cycle Start Date	
Cycle Start Time	
Sterilization start Time	
Sterilization end Time	
Cycle End Time	
Cycle End Date	
Cold Spot Location	
Cold Spot Sensor No.	

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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7.2.29 F₀ CALCULATION

(a) (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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7.2.30 OBSERVATIONS:

Cycle-III :

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

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol to be executed and consisting of following tests.

S.No.	NAME OF TEST OR CHECK	EXECUTED YES /NO	REMARK
1.	CIP		
A	Test for Efficiency of washing Cycle for Manufacturing Vessel& Connected Loop 4000 ltr.		
B	Test for Efficiency of washing Cycle for Manufacturing Vessel& Connected Loop 4000 ltr.		
C	Test for Efficiency of washing Cycle for Manufacturing Vessel& Connected Loop 4000 ltr.		
D	Test for Efficiency of washing Cycle for Holding Vessel & Connected Loop 4000 Ltrs.		
E	Test for Efficiency of washing Cycle for Holding Vessel & Connected Loop 4000 Ltrs.		
F	Test for Efficiency of washing Cycle for Holding Vessel & Connected Loop 4000 Ltrs.		
2.	SIP		
A	Heat distribution study for Manufacturing Vessel & Connected Loop 4000 Ltr.		
B	Heat distribution study for Manufacturing Vessel & Connected Loop 4000 Ltr.		
C	Heat distribution study for Manufacturing Vessel & Connected Loop 4000 Ltr.		
D	Heat Distribution Study For Holding Vessel & Connected Loop 4000 Ltr.		
E	Heat Distribution Study For Holding Vessel & Connected Loop 4000 Ltr.		
F	Heat Distribution Study For Holding Vessel & Connected Loop 4000 Ltr.		
3.	Bio Challenge		
A	Biological challenge Study		



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S.No.	NAME OF TEST OR CHECK	EXECUTED YES /NO	REMARK
B	F ₀ value Calculation		

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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.....

Reviewed By
(Manager QA)
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

9.0 DOCUMENTS TO BE ATTACHED:

- Raw data of Chemical Analysis.
- SIP Print Out
- CIP Print Out

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

16.0 ABBREVIATIONS:

%	:	Percentage
°C	:	Centigrade
BI	:	Biological Indicators
CIP	:	Clean In Place
ID No.	:	Identification Number
IQ	:	Installation Qualification
Ltd.	:	Limited
ml	:	Milliliter
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
QC	:	Quality Control
RPQ	:	Report performance qualification
SAL	:	Sterility assurance level
SIP	:	Sterilization in Place
SLR	:	Spore log reduction
SOP	:	Standard Operating Procedure



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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			