PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE CAPACITY:250 LITER

EQUIPMENT ID No.	
LOCATION	**CIP/SIP ROOM**
DATE OF QUALIFICATION	
SUPERSEDED REPORT NO.	**NIL**

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

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PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

1.0 REPORT PRE APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

2.0 OBJECTIVE:

The objective of this validation report is to establish documented evidence that the CIP-SIP Module 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, associated product line, installed in the CIP/SIP area.

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

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 Control	• Preparation, Review Approval of Reports and submission to Quality Assurance Department. • To conduct Validation activity as per the Approved Protocol. • To provide analytical support for validation activity.
Quality Assurance	• To compile and approval of report. • To monitor all Validation Activities and ensure the Validation is carried out as per the Protocol. • To review Report for completeness and Technical Accuracy.
External Qualification Agency if Applicable)	• Performance of qualification activity as per protocol
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance qualification Activity.
Engineering	• 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 MODULE (250 LITER)

5.0 EQUIPMENT DETAILS:

Equipment Name	**CIP-SIP Module**
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Capacity	**250 L.**
Place of Installation	**CIP/SIP Room**

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Verification of Documents:

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	Executed & approved DQ Protocol Cum Report				
2.	Executed & approved IQ Protocol Cum Report				
3.	Executed & approved OQ Protocol Cum Report				
4.	Executed & approved PQ Protocol				
5.	SOP for Preventive Maintenance of the CIP/SIP Module				
6.	SOP for Operating, Cleaning of the CIP/SIP Module				

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

7.0 TESTS AND CHECKS:

7.2 TEST FOR EFFICIENCY OF WASHING CYCLE FOR MANUFACTURING TANK & CONNECTED LOOP:

Date of Test		**Equipment Name**	
Block		**Equipment ID**	
Area		**Batch Size**	
Tank capacity		**Equipment Make**	
B.No. of NaOH			

CIP Cycle with 5% NaOH

Parameter	Sample No.		
	1st Cycle	2nd Cycle	3rd Cycle
pH			
Conductivity			

CIP Cycle with 10% NaOH

Parameter	Sample No.		
	1st Cycle	2nd Cycle	3rd Cycle
pH			
Conductivity			

CIP Cycle with 15% NaOH

Parameter	Sample No.		
	1st Cycle	2nd Cycle	3rd Cycle
pH			
Conductivity			

ACCEPTANCE CRITERIA:

Sr. NO.	Critical variables	Acceptance criteria
01	pH	5.0 to 7.
02	Conductivity	NMT 1.3 µs

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

Checked By
(Engineering)
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 MODULE (250 LITER)

7.3 TEST FOR EFFICIENCY OF WASHING CYCLE FOR HOLDING TANK & CONNECTED LOOP:

Date of Test		**Equipment Name**	
Block		**Equipment ID**	
Area		**Batch Size**	
Tank capacity		**Make OF Manufacturing Vessel**	
B.No. of NaOH			

CIP Cycle with 5% NaOH

Parameter	**Sample No.**		
	1st Cycle	**2nd Cycle**	**3rd Cycle**
pH			
Conductivity			

CIP Cycle with 10% NaOH

Parameter	**Sample No.**		
	1st Cycle	**2nd Cycle**	**3rd Cycle**
pH			
Conductivity			

CIP Cycle with 15% NaOH

Parameter	**Sample No.**		
	1st Cycle	**2nd Cycle**	**3rd Cycle**
pH			
Conductivity			

ACCEPTANCE CRITERIA:

S.No.	**Critical variables**	**Acceptance criteria**
1.	pH	5.0 to 7.
2.	Conductivity	NMT 1.3 µs

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

Checked By
(Engineering)
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 MODULE (250 LITER)

7.4 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK & CONNECTED LOOP:

Calibration details of Data logger &sensors

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:	
Sterilization Temperature	**122 °C**
Sterilization Hold time	**30 Min.**
Sterilization Reset Temp.	**120.5°C**
Sterilization Stop Temp.	**120.9 °C**
Temp. Hysteresis	**1.0^{0}C**
Purge Time	**60Sec.**

OBSERVATION	**Cycle-1**	**Cycle -2**	**Cycle-3**
Cycle Start Date			
Cycle Start Time			
Cycle End Date			
Cycle End Time			
Sterilization Temperature start time			
Sterilization Temperature end time			

Checked By
(Engineering)
Sign/Date: ……..

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

Inference:……..

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

7.4.1 Fo CALCULATION

A) Numerical F_0 Value:

The actual observations obtained during the heat penetration study 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 (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 (10^0C 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.

$Fo = D_{121} (\log A - \log B)$ …… (b)

Where,

D_{121} D value of the biological indicator at 121^0C
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

$SAL_{desired}$ 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 the biological indicator at 121^0C.

E) ACCEPTANCE CRITERIA:

The calculated numerical Fo value of SIP cycle should be more than the biological indicator value, which is exposed in SIP validation.

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

7.4.2 OBSERVATIONS:

Sr. No.	Probe No.	Sterilizing Temperature (^{o}C)		F_o Value			Checked By Sign/Date
		Max.	Min.	Numerical	BI	SLR Actual	
Cycle – 1st							
Cycle – 2nd							
Cycle – 3rd							

Checked By
(Engineering)
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 MODULE (250 LITER)

7.5 HEAT DISTRIBUTION STUDY FOR HOLDING TANK & CONNECTED LOOP:

Calibration details of Data logger &sensors

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:	
Sterilization Temperature	**122 °C**
Sterilization Hold time	**30 Min.**
Sterilization Reset Temp.	**120.5°C**
Sterilization Stop Temp.	**120.9 °C**
Temp. Hysteresis	**1.0^{0}C**
Purge Time	**60Sec.**

OBSERVATION	**Cycle-1**	**Cycle -2**	**Cycle-3**
Cycle Start Date			
Cycle Start Time			
Cycle End Date			
Cycle End Time			
Sterilization Temperature start time			
Sterilization Temperature end time			

Checked By
(Engineering)
Sign/Date: ……..

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

Inference:……

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

7.5.1 Fo CALCULATION

(a) Numerical F_0 Value:

The actual observations obtained during the heat penetration study 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 (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 (10^0C 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.

$Fo = D_{121} (\log A - \log B)$ …… (b)

Where,

D_{121} D value of the biological indicator at 121^0C
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

$SAL_{desired}$ 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 the biological indicator at 121^0C.

ACCEPTANCE CRITERIA:

The calculated numerical Fo value of SIP cycle should be more than the biological indicator value, which is exposed in SIP validation.

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

7.5.2 OBSERVATIONS:

Sr. No.	Probe No.	Sterilizing Temperature (^{o}C)		F_o Value			Checked By
		Max.	Min.	Numerical	BI	SLR Actual	
Cycle – 1st							
Cycle – 2nd							
Cycle – 3rd							

Checked By
(Engineering)
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 MODULE (250 LITER)

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

Tests Or Checks	Executed [Y/N]	Remark	Verified By (Sign & Date)
Test for Efficiency of washing Cycle for Mixing tank & Connected Loop			
Test for Efficiency of washing Cycle for Holding tank & Connected Loop			
Heat distribution study for mixing Tank & Connected Loop			
Heat Distribution Study For Holding Tank& Connected Loop			
Biological challenge Study			

Checked By
(Engineering)
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 MODULE (250 LITER)

9.0 DOCUMENTS TO BE ATTACHED:

- Raw data of Chemical Analysis.
- Calibration Certificates for Conductivity Meter.
- Calibration Certificates for pH Meter.

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 MODULE (250 LITER)

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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16.0 ABBREVIATIONS:

ml	:	Milliliter
CIP	:	Clean In Place
SIP	:	Sterilization in Place
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
SLR	:	Spore log reduction
SAL	:	Sterility assurance level
%	:	Percentage
°C	:	Centigrade

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (250 LITER)

17.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			`