PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE

CAPACITY:500 LITER

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SUPERSEDED REPORT No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

REPORT CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	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)			

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.

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, authorization and Compilation of Performance qualification Reports • To provide analytical support for validation activity.
Quality Control	• Analytical Support (Microbiological Testing / Analysis)
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).
External Qualification Agency if Applicable)	• Performance of qualification activity as per protocol

5.0 EQUIPMENT DETAILS:

Equipment Name	CIP/SIP Module
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Capacity	500 Ltr.
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 (QA) SIGN/DATE
1.	Executed & approved DQ Protocol Cum Report			
2.	Executed & approved IQ Protocol Cum Report			
3.	Executed & approved OQ Protocol Cum Report			
4.	Approved PQ Protocol			
5.	SOP for Operating, Cleaning of the CIP/SIP Module			
6.	SOP for Preventive Maintenance of the CIP/SIP Module			

Inference:

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

7.0 TESTS AND CHECKS:

7.2 TEST FOR EFFICIENCY OF WASHING CYCLE FOR MANUFACTURING TANK (1000 Ltr.) & 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	Result
pH	
Conductivity	

CIP Cycle with 10% NaOH

Parameter	Result
pH	
Conductivity	

CIP Cycle with 15% NaOH

Parameter	Result
pH	
Conductivity	

ACCEPTANCE CRITERIA:

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

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

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

Inference:

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

7.3 TEST FOR EFFICIENCY OF WASHING CYCLE FOR MANUFACTURING TANK (2000 Ltr.) & 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	Result
pH	
Conductivity	

CIP Cycle with 10% NaOH

Parameter	Result
pH	
Conductivity	

CIP Cycle with 15% NaOH

Parameter	Result
pH	
Conductivity	

ACCEPTANCE CRITERIA:

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

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

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

Inference:

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

7.4 TEST FOR EFFICIENCY OF WASHING CYCLE FOR HOLDING TANK(2000 Ltr.) & 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	Result
pH	
Conductivity	

CIP Cycle with 10% NaOH

Parameter	Result
pH	
Conductivity	

CIP Cycle with 15% NaOH

Parameter	Result
pH	
Conductivity	

ACCEPTANCE CRITERIA:

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

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

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

Inference:

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

7.5 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (1000 Ltr.) & CONNECTED LOOP:

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	Observation
Leak test Pressure	1.50 bar	
Stabilization time	2 Minute	
Leak Test Time	3 minute	
Leak Rate	0.20 bar	
Purging time	030 Second	
Sterilization Pressure	1.50 Bar	
Pressure Dead Band	0.02 bar	
Pulsation temperature	115.0°C	
Sterilization Temperature	122.0 °C	
Heating ON Temperature	123.5 °C	
Heating OFF Temperature	124.0°C	
Sterilization Hold Time	30 Minute	
Sterilization Fail Temperature	120.5^0C	
Overshoot Temperature	127 ^{0}C	
Drain Time	2 Minute	
Cooling Temperature	80 ^{0}C	

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

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

Inference:……..

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

7.5.1 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

OBSERVATION	Cycle-1 Internal	Cycle -2 Internal	Cycle-3 Internal
Cycle Start Date / Time			
Sterilization start Time			
Sterilization end Time			
Total Hold time			
Cycle End Date/ Time			

7.5.2 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-1 External	Cycle -2 External	Cycle-3 External
Cycle Start Date			
Cycle Start Time			
Sterilization start Time			
Sterilization end Time			
Cold Spot Location			
Cold Spot Sensor No.			
Cycle End Time/ Date			

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

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

Inference:……..

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

7.5.3 Fo CALCULATION

(a) (a) Numerical F_0 Value:

Calculate numerical F_0 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) 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 121^0C
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 $SAL_{desired}$ _____

$SLR_{desired}$ =

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,

F_0 : Minimum Calculated $F_{0\ value}$

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

7.5.4 OBSERVATIONS:

Cycle : 01

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Probe No	Sterilizing Temperature (°c)		F_o Value		Spore Log Reduction		Biological Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual	
BET Result :							

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

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

Inference:……..…

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Reviewed By

(Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 02

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 03

Probe No	Sterilizing Temperature (°c)		F_o Value		Spore Log Reduction		Biological Indicator Status
	Maximum	Minimum	Numerical	BI	Desired	Actual	
BET Result :							

Checked By
(Production
Sign/Date: ……..

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

Inference:……..…

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Reviewed By

(Manager QA)
Sign/Date: ……

7.6 HEAT DISTRIBUTION STUDY FOR MANUFACTURING TANK (2000 Ltr.) & CONNECTED LOOP:

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	Observation
Leak test Pressure	1.50 bar	
Stabilization time	2 Minute	
Leak Test Time	3 minute	
Leak Rate	0.20 bar	
Purging time	30 Second	
Sterilization Pressure	1.50 Bar	
Pressure Dead Band	0.02 bar	
Pulsation temperature	115.0°C	
Sterilization Temperature	122.0 °C	
Heating ON Temperature	123.5 °C	
Heating OFF Temperature	124.0°C	
Sterilization Hold Time	30 Minute	
Sterilization Fail Temperature	120.5^0C	
Overshoot Temperature	127 ^{0}C	
Drain Time	2 Minute	
Cooling Temperature	80 ^{0}C	

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

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

Inference:……..

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

7.6.1 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-1 Internal	Cycle -2 Internal	Cycle-3 Internal
Cycle Start Date / Time			
Sterilization start Time			
Sterilization end Time			
Total Hold time			
Cycle End Date/ Time			

7.6.2 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-1 External	Cycle -2 External	Cycle-3 External
Cycle Start Date			
Cycle Start Time			
Sterilization start Time			
Sterilization end Time			
Cold Spot Location			
Cold Spot Sensor No.			
Cycle End Time/ Date			

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

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

Inference:……..

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

7.6.3 Fo CALCULATION

(a) (a) Numerical F_0 Value:

Calculate numerical F_0 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) 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 121^0C
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 $SAL_{desired}$ _____

$SLR_{desired}$ =

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,

F_0 : Minimum Calculated $F_{0\ value}$

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

7.6.4 OBSERVATIONS:

Cycle : 01

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

Inference:

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 02

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

Inference:

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

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 03

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

Inference:……..…

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Reviewed By

(Manager QA)
Sign/Date: ……

7.7 HEAT DISTRIBUTION STUDY FOR HOLDING TANK (2000 Ltr.) & CONNECTED LOOP:

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	Observation
Leak test Pressure	1.50 bar	
Stabilization time	2 Minute	
Leak Test Time	3 minute	
Leak Rate	0.20 bar	
Purging time	030 Second	
Sterilization Pressure	1.50 Bar	
Pressure Dead Band	0.02 bar	
Pulsation temperature	115.0°C	
Sterilization Temperature	122.0 °C	
Heating ON Temperature	123.5 °C	
Heating OFF Temperature	124.0°C	
Sterilization Hold Time	30 Minute	
Sterilization Fail Temperature	120.5^{0}C	
Overshoot Temperature	127 ^{0}C	
Drain Time	2 Minute	
Cooling Temperature	80 ^{0}C	

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

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

Inference:……

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

7.7.1 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL :

OBSERVATION	Cycle-1 Internal	Cycle -2 Internal	Cycle-3 Internal
Cycle Start Date / Time			
Sterilization start Time			
Sterilization end Time			
Total Hold time			
Cycle End Date/ Time			

7.7.2 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR EXTERNAL :

OBSERVATION	Cycle-1 External	Cycle -2 External	Cycle-3 External
Cycle Start Date			
Cycle Start Time			
Sterilization start Time			
Sterilization end Time			
Cold Spot Location			
Cold Spot Sensor No.			
Cycle End Time/ Date			

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

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

Inference:……..

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

7.7.3 Fo CALCULATION

(a) (a) Numerical F_0 Value:

Calculate numerical F_0 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) 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 121^0C
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-

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

$SLR_{desired} =$

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,

F_0 : Minimum Calculated $F_{0\ value}$
D_{121} : D value of the Biological Indicator at 121^0C

7.7.4 OBSERVATIONS:

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 01

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

Inference:……..…

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Reviewed By

(Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 02

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

Inference:

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

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE (500 LITER)	PROTOCOL No.:

Cycle : 03

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

BET Result :

Checked By
(Production
Sign/Date: ……..

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

Inference:

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

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [Y/N]	REMARK
Test for Efficiency of washing Cycle for Mixing tank & Connected Loop		
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 Manufacturing Tank (1000 Ltr.) & Connected Loop		
Heat distribution study for Manufacturing Tank (2000 Ltr.) & Connected Loop		
Heat Distribution Study For Holding Tank (2000 ltr.)& Connected Loop		
Biological challenge Study		

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

Inference:

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

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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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

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)			`