

PROTOCOL No.:

PERFORMANCE QUALIFICATION REPORT FOR CIP-SIP MODULE CAPACITY:500 LITER

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SUPERSEDED REPORT No.	NIL



PROTOCOL No.:

REPORT CONTENTS

S.No.	SUBJECT	PAGE No.
1.0	REPORT PRE APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	6
6.0	PRE-REQUALIFICATION REQUIREMENTS	5
7.0	TESTS & CHECKS	07-30
8.0	CHECK LIST OF ALL TESTS & CHECKS	31
9.0	DOCUMENTS TO BE ATTACHED	32
10.0	NON-COMPLIANCE	32
11.0	DEVIATION FROM PRE DEFINED SPECIFICATION	32
12.0	CHANGE CONTROL	32
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	33
14.0	CONCLUSION	32
15.0	RECOMMENDATION	32
16.0	ABBREVIATION	34
17.0	REPORT POST APPROVAL	35



PROTOCOL N	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)			



PROTOCOL No.:

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.



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, authorization and Compilation of Performance qualification Reports To provide analytical support for validation activity. 	
Quality Control	Analytical Support (Microbiological Testing / Analysis)	
Quanty Control	7 marytical support (Microbiological Testing / Marysis)	
D 1 (1	Review of Performance Qualification Report.	
Production	To co-ordinate and support Performance qualification Activity.	
	Review of Performance Qualification Report.	
Engineering	To co-ordinate and support Validation Activity.	
	Responsible for Trouble shooting during execution (If Occurs).	
External Qualification Agency	Performance of qualification activity as per protocol	
if Applicable)	2 51.51 31 quantitation activity as per protector	



PROTOCOL No.

5.0	EOUIPN	MENT	DETA	ILS:
•••				

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:	
	n : In
	Reviewed By
	(Manager QA)
	Reviewed By (Manager QA) Sign/Date:



P	R	O	\mathbf{T}	0	\mathbf{C}	O.	L	N	o.	:
---	---	---	--------------	---	--------------	----	---	---	----	---

7.0	TESTS	AND	CHECK	S
/.U	16515	AND	CHECK	ď.

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
рН	
Conductivity	

ACCEPTANCE CRITERIA:

	110 022 112 102 012 2121			
Sr.	Critical variables	Acceptance criteria		
NO.				
01	pH	5.0 to 7.		
02	Conductivity	NMT 1.3 μs		



PROTOCOL No	•

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager QA) Sign/Date:
	Sign/Date:



PRO'	TOCO	DL No.:
------	------	---------

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
pН	
Conductivity	

CIP Cycle with 10% NaOH

Parameter	Result
pН	
Conductivity	

CIP Cycle with 15% NaOH

Parameter	Result
pН	
Conductivity	

ACCEPTANCE CRITERIA:

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



PROTOCOL No	•

THE THEORY IN THE STATE OF THE	
Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



P	R	0	\mathbf{T}	0	\mathbf{C}	\mathbf{O}	L	N	o.	:

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
pН	
Conductivity	

CIP Cycle with 10% NaOH

Parameter	Result
pH	
Conductivity	

CIP Cycle with 15% NaOH

Parameter	Result
pН	
Conductivity	

ACCEPTANCE CRITERIA:

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



	_		\sim	~-		
VV.	1 Y I	' <i> </i> 1	Y Y	11	. No	•
	、 ,,			. , .	/ I TU	

TIMMINI DE VIED	
Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
•	
	Reviewed By (Manager QA) Sign/Date:



PR	$\mathbf{\Omega}$	T	\mathbf{a}	α	\cap	Г	N	_	
۲ĸ	()	1	w	U			IN	O.	. :

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

Test Instrument Name	Model	l No	Calibration done Date	
Sensors type & Qty.	Make		Calibration due Date	
Name of Cycle		Heat Distribution St	tudv	

Name of Cycle		Heat Distribution Study					
Date of test				Equipment Make			
Equipment Name				Equipment ID			
Capacity of vessel				Equipment Loc	cation		
Set Parameters:		A	cceptan	ce Criteria		Observation	
Leak test Pressure			1.50) bar			
Stabilization time			2 M	inute			
Leak Test Time	ak Test Time		3 minute				
Leak Rate			0.20	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	terilization Hold Time			30 Minute			_
Sterilization Fail Temperat	rature			$0.5^{\circ}\mathrm{C}$			
Overshoot Temperature		127 °C				_	
Drain Time		2 Minute					
Cooling Temperature		-	80	0°C			_

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	-
	Reviewed By
	(Manager QA)
	Sign/Date:

7.5.1 SUMMARY DETAIL FOR STERILIZATION PROCESS FOR INTERNAL:



Cycle Start Time

Sterilization start Time
Sterilization end Time
Cold Spot Location
Cold Spot Sensor No.

Cycle End Time/ Date

PRO)TC	COL	No.

OBSERVATION	Cycle-1	Cycle -2	Cycle-3					
	Internal	Internal	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	Cycle -2	Cycle-3					
	External	External	External					
Cycle Start Date								

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



PROTOCOL No.:

7.5.3 Fo CALCULATION

(a) (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}

D₁₂₁ D value of the Biological Indicator at 121^oC

7.5.4 OBSERVATIONS:

Cycle: 01



PR	\mathbf{O}'	T(C	()I	[,]	N	n.	•

Probe No	Tempe	Sterilizing Temperature (°c)		F _o Value		Reduction	Biological
1 Tobe No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
ı							
BET Resu	lt:		•				
Checked E (Production Sign/Date:	on)	•••••					By Assurance) e:
						Reviewed	 I Rv
•							
						(Manage Sign/Date	r QA) e:



P	R	Γ	\mathbf{O}	CO	L	No.
Г.	\mathbf{r}	<i>J</i> J	U	CU	L	INU.

Cycle: 02							
Probe No		Sterilizing Temperature (°c)		F _o Value		g Reduction	Biological
Tobe No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
ET Resul	I 4 .						
Productio ign/Date:		••••••					Assurance) te:
iference:							
						Reviewe	d Rv
						(Manage	er QA)
						Sign/Da	te:



PROTOCOL No

Cycle : 03								
Probe No	Tempe	Sterilizing Temperature (°c)		F _o Value		Reduction	Biological	
1 TODE IN	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status	
DEE D								
BET Resul	lt:							
Checked By (Production (Quality Assurance) Sign/Date: Sign/Date:								
Inference:								
				•••••	•••••			
•						Reviewed	By	
						(Manager Sign/Date	r QA)	



PR	$\boldsymbol{\cap}$	T	\mathbf{a}	α	\cap	Г	N	_	
rk	()	1	w	U	. ,		1	O.	.:

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

LOOI.								
Test		Model No			Calibration			
Instrument Name		M I			G 101 41			
Sensors type & Qty.		Make Calib			Calibration	oration due Date		
Name of Cycle		Heat Distribution Study						
Date of test		Equipment Make			Make			
Equipment Name		Equipment ID						
Capacity of vessel		Equipment Location						
Set Parameters:		Ac		ce Criteria		Observation		
Leak test Pressure			1.50) bar				
Stabilization time			2 M	inute				
Leak Test Time			3 m	inute				
Leak Rate			0.20) bar				
Purging time			30 S	econd				
Sterilization Pressure			1.50) Bar				
Pressure Dead Band			0.02	2 bar				
Pulsation temperature			115	.0°C				
Sterilization Temperature	9	122.0 °C						
Heating ON Temperature		123.5 °C						
Heating OFF Temperatur	·e	124.0°C						
Sterilization Hold Time		30 Minute						
Sterilization Fail Tempera	ature	120.5°C						
Overshoot Temperature		127 °C						
Drain Time			2 M	inute				
Cooling Temperature			80	0°C				
Checked By (Production)						erified By Quality Assu	ırance)	
Sign/Date:						Sign/Date:		
Inference:	••••••	• • • • • • • • • • • • • • • • • • • •	•••••	••••••	••••••	•••••	•••••	
•••••	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	••••••••	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	
•••••	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••••			•••••	
				(N	eviewed By Ianager QA gn/Date:	·		



_	_	\sim	-	\sim	\sim	_	_			
ν	v	<i>1</i> 1	ч,	<i>(</i> 1	\mathbf{C}	1			Λ	•
L	1/	ι,		ι,	·	.,		1.1	w	

OBSERVATION	Cycle-1	Cycle -2	Cycle-3
	Internal	Internal	Internal
Cycle Start Date / Time			
Sterilization start Time			
Sterilization end Time			
Total Hold time			
Cycle End Date/ Time			
OBSERVATION			
ODSERVATION	Cycle-1	Cycle -2	Cycle-3
ODSERVATION	Cycle-1 External	Cycle -2 External	Cycle-3 External
			•
			•
Cycle Start Date Cycle Start Time			•
Cycle Start Date Cycle Start Time Sterilization start Time			•
Cycle Start Date Cycle Start Time Sterilization start Time Sterilization end Time			•
Cycle Start Date Cycle Start Time Sterilization start Time Sterilization end Time Cold Spot Location			•
Cycle Start Date Cycle Start Time Sterilization start Time Sterilization end Time Cold Spot Location Cold Spot Sensor No.			•
Cycle Start Date Cycle Start Time Sterilization start Time Sterilization end Time Cold Spot Location Cold Spot Sensor No. Cycle End Time/ Date		External	External
Cycle Start Date		External	External

Checked By (Production)	Verified By (Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



PROTOCOL No.:

7.6.3 Fo CALCULATION

(a) (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) 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

7.6.4 OBSERVATIONS:

Cycle: 01



PROTOCOL No	•

D I W		rilizing rature (°c)	F _o V	alue	Spore Log	Reduction	Biological
Probe No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
BET Resul	lt:						
Checked B	\mathbf{g}					Verified 1	Ву
(Productio	n					(Quality)	Assurance)
Sign/Date:	•••••	••••••				Sign/Date	
Inference:							
•••••	• • • • • • • • • • • • • • • • • • • •	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	••••••
•••••	• • • • • • • • • • • • •	•••••	•••••	•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	••••••
•	• • • • • • • • • • • • •	•••••	••••••	•	• • • • • • • • • • • • • • • • • • • •	Reviewed	Bv
						(Manage	
						Sign/Date	······································



Cycle: 02

Cycle . 02							
D 1 N	Sterilizing Temperature (°c)		Sterilizing F _o Value		Spore Log	Reduction	Biological
Probe No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
DEW D							
BET Resul	It :						
Checked B (Production Sign/Date:	n					Verified I (Quality A Sign/Date	By Assurance) e:
Inference:							
			••••••			Reviewed	 I Rv
						(Manager	r QA)
						Sign/Date	2



Cycle: 03

Cycle . 03							
D. J. M.	Ster Tempe	Sterilizing F ₀ Value		alue	Spore Log	Reduction	Biological
Probe No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
2222	-						
BET Resul	lt:						
Checked By (Production (Quality Assu Sign/Date: Sign/Date:							
Inference:							
•	• • • • • • • • • • • • • • • • • • • •		••••••			Reviewed	Ву
						(Manager	
							· · · · · · · · · · · · · · · · · · ·
						Ü	



	_		\sim	_		-	
PR	1 Y	1 ' <i>1</i> 1	V '		l N		•
1 IX	.,			.,,	1 / 1	7U.	

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

Test Instrument Name		Model N	0		Calibration do	ne Date	
Sensors type & Qty.					Calibration du	e Date	
Name of Cycle]	Heat Di	stribution Stu	dy		
Date of test				Equipment M	lake		
Equipment Name				Equipment II)		
Capacity of vessel				Equipment L	ocation		
Set Parameters:		Aco	ceptanc	e Criteria	0	bservatio	n
Leak test Pressure			1.50	bar			
Stabilization time			2 M	inute			
Leak Test Time			3 mi	inute			
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 Temperatur	e	124.0°C					
Sterilization Hold Time		30 Minute					
Sterilization Fail Tempera	ature	120.5°C					
Overshoot Temperature		127 °C					
Drain Time		2 Minute 80 °C					
Cooling Temperature			80	<u>°C</u>			
					X 7•4	*. I D	
Checked By Production)						ied By	ron oo)
Froduction) Sign/Date:						ality Assu /Date:	
ign/Date:	• • • • •				Sign	/Date:	•••••
nference:							
						ewed By	
				(Mar	ager QA)		
						Date:	



					_
PR(vT	~~	7	T N	[
PKI	, ,	,,,			(I).

OBSERVATION	Cycle-1	Cycle -2	Cycle-3
	Internal	Internal	Internal
Cycle Start Date / Time			
Sterilization start Time			
Sterilization end Time			
Total Hold time			
Cycle End Date/ Time			
OBSERVATION	Cycle-1	Cycle -2	Cycle-3
	External	External	Externa
Cycle Start Date			
Cycle Start Time			
Sterilization start Time			
Sterilization end Time			
Cold Spot Location			
Cold Spot Sensor No.			
Cycle End Time/ Date			
Cycle End Time/ Date		T7 100 X	D.
<u> </u>		Verified	By Assurance)

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



PROTOCOL No.:

7.7.3 Fo CALCULATION

(a) (a) Numerical F_0 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

 $SLR_{Actual} = F_0 / D_{121} \underline{\hspace{1cm}}$

SLR Actual =

Where,

 F_0 : Minimum Calculated F_0 value

D₁₂₁ D value of the Biological Indicator at 121^oC

7.7.4 OBSERVATIONS:



Cycle: 01

Cycle: 01							
Probe No	Ster Tempe	rilizing rature (°c) Minimum	F _o Value		Spore Log	Reduction	Biological
11000110	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
DEC D							
BET Resul	lt:						
Checked By (Production (Quality Assurance) Sign/Date: Sign/Date:							
Inference:							
•••••							
•	• • • • • • • • • • • • • • • • • • • •					Reviewed	Ву
						(Manager	r OA)
							·
						-	



P	R	Γ	\mathbf{O}	CO	L	No.
Г.	\mathbf{r}	<i>J</i> J	U	CU	L	INU.

Cycle: 02							
Probe No	Sterilizing Temperature (°c)		Fo Value		Spore Log	Reduction	Biological
1100e No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
BET Resu	lt:						
Checked B (Production Sign/Date:	n					Verified I (Quality / Sign/Date	By Assurance) e:
Inference:							
•••••		••••••		•••••	• • • • • • • • • • • • • • • • • • • •		
•••••	• • • • • • • • • • • • • • • • • • • •	•••••		•••••	• • • • • • • • • • • • • • • • • • • •	Reviewed	Bv
						(Manager	



Cycle: 03

Cycle . 03							
D. L. M.	Sterilizing Temperature (°c)				Spore Log	Reduction	Biological
Probe No	Maximum	Minimum	Numerical	BI	Desired	Actual	Indicator Status
BET Resul	lt:						
Checked B	$\mathbf{s}\mathbf{y}$					Verified I	
(Production Sign/Date:							Assurance)
Sign/Date:	•••••	• • • • • • • • • • • • • • • • • • • •				Sign/Date	
Inference:							
•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	•••••	•••••	••••••	•••••
•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	•••••	•••••	••••••	•••••
••••••	• • • • • • • • • • • • •	•••••••	••••••	•••••••	••••••	Reviewed	By
						(Manager	
						Sign/Date	



P	R	O	T	a	C	U.	T.	N	^	
	N	v		w		.,		17	Q).	

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		

Inference:	Verified By (Quality Assurance) Sign/Date:
	Reviewed By
	(Manager QA)
	Sign/Date:



PROTOCOL No.	•

9.0 DOCUMENTS TO BE ATTACHED:

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

•	Canoration Certificates for pri Meter.
10.0	NON COMPLIANCE:
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:
12.0	CHANGE CONTROL, IF ANY:



PR(T	\mathbf{OC}	OL	No.:

1 11/1	NVII DE VIEG
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):
440	
14.0	CONCLUSION:
4=0	
15.0	RECOMMENDATION:



PROTOCOL No.:

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



PROTOCOL No.

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)			