OPERATIONAL QUALIFICATIONFOR

FOR PLC SYSTEM OF

PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Equipment Name	Purified Water Distribution Loop System
Equipment ID	
System Location	Water Syssem
Effective Date	

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

TABLE OF CONTENT

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1. PRE APPROVALS:

The signature listed below indicates the pre-approval of this operational qualification. This approval is joint responsibility of listed functional areas.

Function	Name	Department	Designation	Signature & Date
	…………..			
Prepared by		Engineering		
	……………..			
Reviewed by		Engineering		
Reviewed by		Production		
Reviewed by		Quality Assurance		
	………………			
Approved by		Quality Assurance		

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

2. OBJECTIVE:

The objective of operational qualification is to collect the sufficient data pertaining to Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System installed and define the operational qualification requirements and acceptance criteria for the Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System supporting automation of the system. Successful completion of these operational qualification requirements will provide assurance that the Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System was installed successfully as Per Approved Change Control.

3. SCOPE:

This document is applicable to Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System is installed. This operational qualification shall define the documentation, references and acceptance criteria to establish that the Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System is installed in accordance with the guidelines laid down by the manufacturer of the system.

4. SYSTEM DESCRIPTION:

Equipment Name	:	Purified Water Distribution Loop System
Supplier / Manufacturer	:	
Equipment ID. No.	:	
Location	:	Water System

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5.   CONTROL SYSTEM SCHEMATIC DIAGRAM

The PLC System schematic diagram for the "**Purified Water Distribution Loop System**" automation is given below:
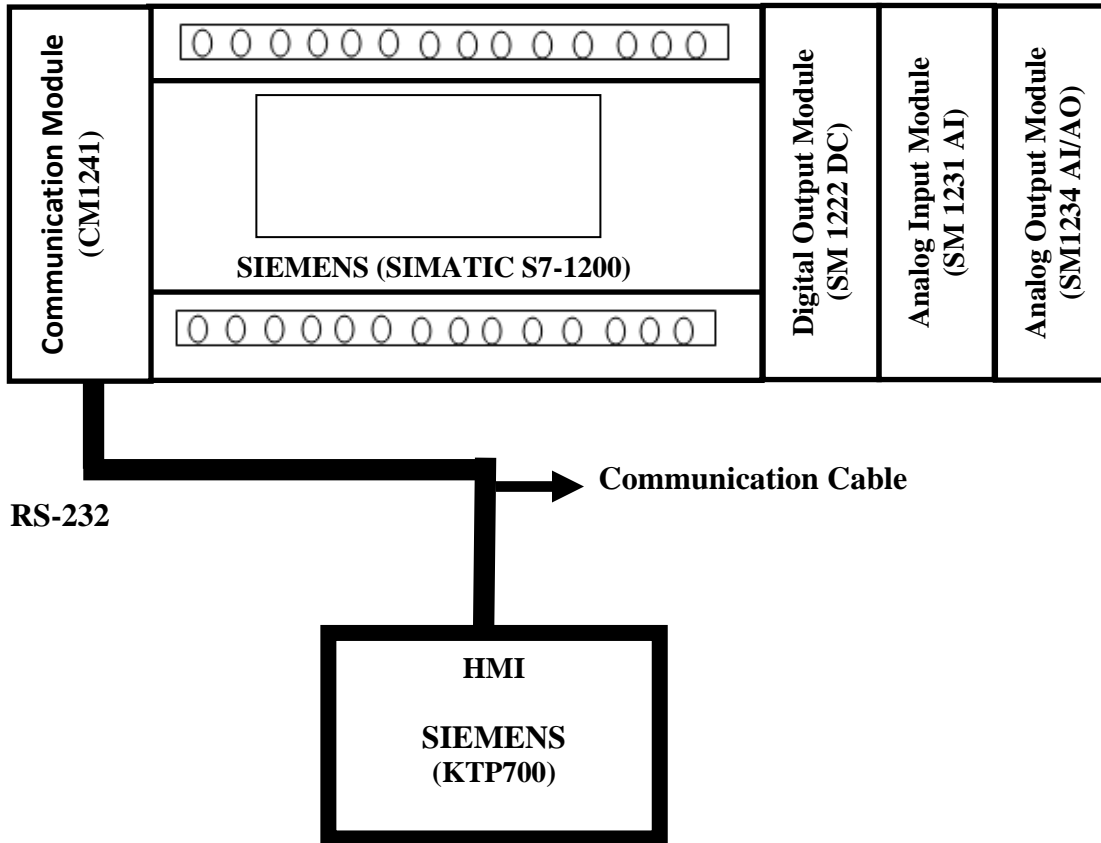
OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

6. SIGNATURE OF VALIDATION TEAM

All the executer involved in this documents have to sign within prescribed format given below.

M/s …………..

Name	Designation	Department	Date

M/s …………..

Name	Designation	Department	Signature/Date

7. REVISION HISTORY

Date	Supersedes	Reason for Revision
NA	NA	NA.

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

8. ROLE AND RESPONSIBILITY:

The validation team comprising of representative from each of the following departments should be responsible for overall compliance with this validation plan.

Department	Responsibilities
Validation Agency	➤ To collect the necessary data for operational qualification activities. ➤ To prepare and execute the operational qualification coordination with engineering, validation and quality assurance team. ➤ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle. ➤ To submit operational qualification for approval.
Engineering	➤ To provide the necessary data for operational qualification activities. ➤ To review and approve the operational qualification.
Production	➤ To provide the necessary data for operational qualification activities. ➤ To review and approve the operational qualification.
Quality Assurance	➤ To review and approve the operational qualification.

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9. REFERENCES

The publication listed below form part of this reference documents. Each publication shall have latest revision in effect on the date of this document is approved for execution.

GAMP 5	Good Automated Manufacturing Practices, Version 5, Guideline Document for Automated Systems from International Society of Pharmaceutical Engineering
21 Code of Federal Regulations (CFR), Part 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding off Drugs; General
21 Code of Federal Regulations (CFR), Part 211	Current Good Manufacturing Practice for finished Pharmaceuticals
21 Code of Federal Regulations (CFR), Part 11	21 Code of Federal Regulations (CFR), Part 11 Electronic Records, Electronic Signatures, Final Rule Electronic Submissions; Establishment of Public Docket, Notice
ICH Q9	International Conference of Harmonization (ICH) quality risk assessment Q9
EU GMP	Laying down the principles and guidelines of GMP in respect of medicinal products for human use.
IQ	Installation Qualification

10. DOCUMENTATION PROCEDURE

- Qualification activities will be performed as defined in the approved document.
- All documentation will be completed during the execution of the qualification.
- Recording of information will be made in permanent ink.
- Fill out complete information in the verification table provided.
- Do not keep any space blank. Mark blank space with a single line throughout the appropriate space with mentioning NA (Not Applicable) and put initial and date.
- Correct the mistakes by drawing a single line through the incorrect data, recording the correct information and then initialing and dating the change.

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11. QUALIFICATION COMPLETION AND APPROVAL:

- Verify that all tests required by qualification are completed and attached.

- Verify that all amendments and discrepancies are documented, approved and attached.

- If all items in the qualification for the Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

12. ACCEPTANCE CRITERIA:

- Installation of the Programmable logic controller (PLC) and HMI Based system of Purified Water Distribution Loop System with suitable utility connections.

- Installation completion as per manufacturer's recommendations &cGMP requirements.

- Installation of major components as per the design specifications.

- The supply of all necessary documentation from manufacturer.

- The operational capabilities of system demonstrated.

- The system is operating as intended and is under state of control.

- Operational features meet system requirements and system specifications.

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

13. Training Record:

Following persons have been trained on this approved qualification document and will execute/ help in execution of this Qualification document.

Duration of training:

Venue of training: **Date of training**:

Sr. No.	Name of Trainee	Designation of Trainee	Signature of Trainee	Evaluation OK/ To be retrained	Signature of evaluator

Trainer details		
Name	**Designation**	**Signature**

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14. OPERATIONAL VERIFICATION TEST
14.1   Verification of Field Instruments Calibration Details

Objective	:	To verify the field instruments certificate.
Tools Required	:	Not Applicable
Procedure	:	1. Verify Instruments Name & ID.
		2. Verify Instruments Calibration Done Date & Due Date.
Acceptance	:	Fields instruments should be calibrated.
Criteria		

Verification Table:

Refer Attachment No.1					
Sr. No.	Instruments Name	Instruments ID	Calibration Done Date	Calibration Due Date	Discrepancy? (Yes/No)	Done By Sign & Date
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by	: _____	Sign & Date	: _____
Verified by (Engg.)	: _____	Sign & Date	: _____
Reviewed by (QA)	: _____	Sign & Date	: _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.2 Verification of PLC LED's:

Objective   :   To verify the normal LED'S indication of PLC.

Tools Required   :   Not Applicable

Procedure   :   1. Switch ON the PLC System

                         2. Record LED indication on PLC.

Acceptance   :   LED indication shall match with specified results in verification table.
Criteria

Verification Table:

Description	LED Indication	Observation	Discrepancy? (Yes/No)	Done By Sign & Date
PLC				
RUN/STOP	ON			
ERROR	OFF			
MAINT	OFF			

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.3 Verification of PLC Input and Output

Objective	:	To verify the PLC input and output.
Tools Required	:	Universal Source
Procedure	:	1. Simulate each digital input signal by doing shorting and opening of signal to Control input and record Input Voltage at terminal.
		2. Simulate each digital output signal by operating the output using the HMI and record the Output Voltage at terminal.
		3. Simulate each analog input signal by giving analog signal from the source and record the value of input on.
		4. Simulate each analog output signal by operating the output using the IPC and record the status of output on.
Acceptance Criteria	:	All inputs and outputs must be verified to meet wiring diagram of Control system and function as per design document.

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.3.1 Verification Table: DigitalInput/Output

PLC Channel	IO Description	Specified LED Status		Observation LED Status	Discrepancy? (Yes/No)	Done By Sign & Date
SIMATIC S7-1200 (Input)						
X0	EMERGANCY STOP	ON	OFF			
X1	HOOTER RESET	ON	OFF			
X2	AIR PRESSURE	ON	OFF			
X3	PWD AUTO/MAN SWITCH	ON	OFF			
X4	P-108.01/02 TRIP	ON	OFF			
X5	P-108.01/02 RUN	ON	OFF			
X6	PHASE FAIL	ON	OFF			
X7	RD-108.01	ON	OFF			
X8	SAPARE	NA	NA			
X9	SAPARE	NA	NA			
X10	SAPARE	NA	NA			
X11	SAPARE	NA	NA			
X12	SAPARE	NA	NA			
X13	SAPARE	NA	NA			
SIMATIC S7-1200 (Output)						
Y0	V-107.06 INLET VALVE	ON	OFF			
Y1	V-108.10	ON	OFF			
Y2	V-108.08	ON	OFF			
Y3	V-108.09	ON	OFF			
Y4	V-108.06	ON	OFF			
Y5	V-108.11	ON	OFF			
Y6	EVF-108.01	ON	OFF			
Y7	P-108.01	ON	OFF			
Y8	P-108.02	ON	OFF			
Y9	UV-108.01	ON	OFF			
SIMATIC S5 1222 DC (Output)						

PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

PLC Channel	IO Description	Specified LED Status		Observation LED Status		Discrepancy? (Yes/No)	Done By Sign & Date
Y10	V-108.05	ON	OFF				
Y11	HOOTER	ON	OFF				
Y12	VFD RESET	ON	OFF				
Y13	V-108.04	ON	OFF				
Y14	SPARE VALVE-1	NA	NA				
Y15	SPARE	NA	NA				

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14.3.2 Verification Table: Analog Input

PLC Address	Details	Input Signal	Expected Process Reading	Actual Process Reading	Meets acceptance criteria		Sign. & date
					Yes	**No**	
Module SM 1231							
AI1	TT 108.03 (ºC)	4.000 mA	0.0 (ºC)		( )	( )	
		12.000 mA	75.0 (ºC)		( )	( )	
		20.000 mA	150.0 (ºC)		( )	( )	
AI2	LT 108.01 (LTR)	4.000 mA	0 (LTR)		( )	( )	
		12.000 mA	2500 (LTR)		( )	( )	
		20.000 mA	5000 (LTR)		( )	( )	
AI3	TT 108.01 (ºC)	4.000 mA	0.0 (ºC)		( )	( )	
		12.000 mA	75.0 (ºC)		( )	( )	
		20.000 mA	150.0 (ºC)		( )	( )	
AI4	IM-108.01 (W/m2)	4.000 mA	0(W/m2)		( )	( )	
		12.000 mA	50(W/m2)		( )	( )	
		20.000 mA	100(W/m2)		( )	( )	
AI5	FT-108.01 (LPH)	4.000 mA	0 (LPH)		( )	( )	
		12.000 mA	5000 (LPH)		( )	( )	
		20.000 mA	10000 (LPH)		( )	( )	
AI6	CT 108.01(Us/cm)	4.000 mA	0.0 (Us/cm)		( )	( )	
		12.000 mA	5.0 (Us/cm)		( )	( )	
		20.000 mA	10.0 (Us/cm)		( )	( )	
AI7	TT-108.02 (ºC)	4.000 mA	0.0 (ºC)		( )	( )	
		12.000 mA	75.0 (ºC)		( )	( )	
		20.000 mA	150.0 (ºC)		( )	( )	
AI8	TOC-108.01(PPB)	4.000 mA	0.0 (PPB)		( )	( )	
		12.000 mA	250.0 (PPB)		( )	( )	
		20.000 mA	500.0 (PPB)		( )	( )	
AI9	SPARE	NA	NA		( )	( )	
AI10	SPARE	NA	NA		( )	( )	

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14.3.1 Verification Table: Analog Output

PLC Address	Details	Set value from HMI	Output Signal	Actual Reading	Meets acceptance criteria		Sign. & date
					Yes	**No**	
Module SM 1234							
AO1	VFD P-108.01/02 (HZ)	0.0 (HZ)	4.000 mA		( )	( )	
		30.0(HZ)	12.000 mA		( )	( )	
		60.0(HZ)	20.000 mA		( )	( )	
AO2	SPARE	NA	NA		( )	( )	

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.4   Verification of Password Security

Objective	:	To verify the password security as defined.
Tools Required	:	Not Applicable
Procedure	:	1. Try to login with wrong password.
		2. Login with correct password.
		3. Check all the result with specified data given in verification table.
Acceptance Criteria	:	All the test result shall match with specified result.

A.) Verification Table for Password Security   :

Refer Attachment No.2			
Description	**Specified**	**Discrepancy? (Yes/No)**	**Done By Sign & Date**
Wrong User ID & Password Entry at Operator Level	System shall be Generate the wrong password or user name popup.		
Correct User ID & Password Entry at Operator Level	Operator login the system successfully.		
Wrong User ID & Password Entry at Supervisor Level	System shall be Generate the wrong password or user name popup		
Correct User ID & Password Entry at Supervisor Level	Supervisor login the system successfully.		
Wrong User ID & Password Entry at Manager Level	System shall be Generate the wrong password or user name popup		
Correct User ID & Password Entry at Manager Level	Manager login the system successfully.		
Wrong User ID & Password Entry at Admin Level	System shall be Generate the wrong password or user name popup		
Correct User ID & Password Entry at Admin Level	Admin login the system successfully.		

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by	: _____	Sign & Date	: _____
Verified by (Engg.)	: _____	Sign & Date	: _____
Reviewed by (QA)	: _____	Sign & Date	: _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.5   Verification of User Level and Rights.

Objective   :   To verify the user level and rights as defined.

Tools Required   :   Not Applicable

Procedure   :   1.   Verification of User level.

                               2.   Login with each level and check all rights/screen.

                               3.   Matched the result with privileges in test verification table.

Acceptance   :   All the result shall match with user rights/screen and level.
Criteria

Verification Table for User Rights

Refer Attachment No.3				
Right /Screen	**Operator Level**	**Supervisor Level**	**Manager Level**	**Admin Level**	**Done By Sign &Date**
Page No.					
Welcome Screen	☐	☐	☐	☐	
PW Menu Screen	☐	☐	☐	☐	
Alarm Screen	☐	☐	☐	☐	
PW Input Screen-1	☐	☐	☐	☐	
PW Input Screen-2	☐	☐	☐	☐	
PW Output Screen	☐	☐	☐	☐	
Password Screen	☐	☐	☐	☐	
PW Set Parameter Screen	☐	☐	☐	☐	
PW Set Parameter Screen Edit	☐	☐	☐	☐	
PW Sanitization Parameter Screen	☐	☐	☐	☐	
PW Sanitization Parameter Screen Edit	☐	☐	☐	☐	
PID Screen	☐	☐	☐	☐	
PID Screen Edit	☐	☐	☐	☐	
PW Scalling-1(AI)Screen	☐	☐	☐	☐	

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Right /Screen	Operator Level	Supervisor Level	Manager Level	Admin Level	Done By Sign &Date
Refer Attachment No.3					
Page No.					
PW Scalling-1(AI)Screen Edit	☐	☐	☐	☐	
PW Scalling-2(AI)Screen	☐	☐	☐	☐	
PW Scalling-2(AI)Screen Edit	☐	☐	☐	☐	
Date and Time Screen	☐	☐	☐	☐	
Date and Time Screen Edit	☐	☐	☐	☐	
PW MIMIC Screen	☐	☐	☐	☐	
PW Settable Timer Screen	☐	☐	☐	☐	
PW Settable Timer Screen Edit	☐	☐	☐	☐	
PW Mode Selection Screen	☐	☐	☐	☐	
Printing Screen	☐	☐	☐	☐	
Printing Screen Edit	☐	☐	☐	☐	

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.6   Verification of HMIScreens

Objective	:	To verify the HMI screens as defined.	
Tools Required	:	Not Applicable	
Procedure	:	1	Check all programmable function keys for their actual response in each screen.
		2	Check Function Key Command are properly programmed by operating output devices.
		3	Verify the display on HMI with actual machine conditions.
		4	List up the screen and attached the screen shot in attachment
Acceptance Criteria	:	All the programmable function keys and touch keys shall be work as per assign function.	

HMI Screen Verification Table:

Refer Attachment No.4				
Sr. No.	**HMI Screen**	**Refer Attachment No.4 Screen No.**	**Discrepancy? (Yes/No)**	**Done By Sign & Date**
1	Welcome Screen			
2	PW Menu Screen			
3	Alarm Screen			
4	PW Input Screen-1			
5	PW Input Screen-2			
6	PW Output Screen			
7	Password Screen			
8	PW Set Parameter Screen			
9	PW Sanitization Parameter Screen			
10	PID Screen			
11	PW Scalling-1(AI) Screen			
12	PW Scalling-2(AI) Screen			
13	Date and Time Screen			
14	PW MIMIC Screen			
15	PW Settable Timer Screen			
16	PW Mode Selection Screen			
17	Printing Screen			

Remarks:

_____

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_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.7   Verification of Set Parameter Boundary Condition

Objective   :   To verify the set parameter boundary condition as defined.

Tools Required   :   Not Applicable

Procedure   :   1.   Enter minimum value for the given span and observe the response.

2.   Enter maximum value for the given span and observe the response.

3.   Enter value above and below the acceptable span and observe the response

Acceptance Criteria   :   System must accept value which is within the range and criteria for minimum/maximum reject values are given below

1.   . For Integer Value

Reject Value (minimum) = Acceptable Value (minimum) – 1

Reject Value (Maximum) = Acceptable Value (maximum) + 1

2.   For Decimal Value

Reject Value (minimum) = Acceptable Value (minimum) - 0.1

Reject Value (Maximum) = Acceptable Value (maximum) + 0.1 and so on

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Verification Table:

Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No	Done By Sign & Date
PW Set Parameter											
Return Loop Temp. TT-108.02 Low Low (ºC)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Return Loop Temp. TT-108.02 Low (ºC)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Return Loop Temp. TT-108.02 High (ºC)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Return Loop Temp. TT-108.02 High High (ºC)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
IM-108.01 Low (W/m2)	0 to 100		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Conductivity CT-108.01 High (μS/cm)	0.00 to 10.00		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Return Loop FT-108.01 Low (LPH)	0.0 to 10000.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Return Loop FT-108.01 High (LPH)	0.0 to 10000.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
TOC-108.01 High (Alert) (PPB)	0.0 to 500.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
TOC-108.01High Action (PPB)	0.0 to 500.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
LT-108.01 LL	0 to 5000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
LT-108.01 LH	0 to 5000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No)	Done By Sign & Date
LT-108.01 HL	0 to 5000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
LT-108.01 HH	0 to 5000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PW Sanitization Parameter											
PW Tank-TT 108.01 Low Low (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PW Tank-TT 108.01 Low (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PW Tank-TT 108.01 High (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Loop Return TT-108.02 Low Low (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Loop Return TT-108.02 Low (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Loop Return TT-108.02 High (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Loop Return TT-108.02 High High (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Vent Filter TT-108.03 Low Low(°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Vent Filter TT-108.03 Low (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Vent Filter TT-108.03 High (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No)	Done By Sign & Date
Vent Filter TT-108.03 High High (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Sanitization Process											
Sanit Abort Time Set (SEC)	0 to 9999		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Sanitization Frequency Set (HZ)	0.00 to 60.00		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Sanitization Tank Level Set (LTRS)	0 to 5000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Sanitization Time Set (MIN)	0 to 999		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PID Screen											
Gain	0 to 99		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Integral Time	0 to 99		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Derivative Time	0 to 99		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PW Scalling-1 (AI)											
TT-108.03 (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
LT-108.01 (LTR)	0 to 5000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
TT-108.01 (°C)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No)	Done By Sign & Date
IM-108.01 (W/m2)	0 to 100		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
FT-108.01 (LPH)	0 to 10000		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
CT-108.01 (µS/cm)	0.0 to 10.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PW Scalling-2 (AI)											
TT-108.02 (ºC)	0.0 to 150.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
TOC-108.01(PPB)	0.0 to 500.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Analog Output											
VFD P-108.01/02 (HZ)	0.0 to 60.0		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
PW Settable Timer											
IM-108.01 Low Time Set (SEC)	0 to 999		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
CT-108.01 High Time Set(SEC)	0 to 999		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
TOC-108.01 High Time Set(SEC)	0 to 999		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
FT-108.01 Low Time Set(SEC)	0 to 999		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		Yes☐ No ☐		
Printing Screen											
Interval SET (Min)	0 to 999		Yes☐		Yes☐		Yes☐		Yes☐		

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No)	Done By Sign & Date
			No ☐		No ☐		No ☐		No ☐		

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.8 Verification of Alarms and Interlocks

Objective	:	To verify the alarms and interlocks as defined.
Tools Required	:	Not Applicable
Procedure	:	1. Check all the test given in verification table.
		2. Record the result in verification table.
Acceptance Criteria	:	All the test result shall match with expected result.

Verification Table:

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When Sanitization Timer Start	"**SANITIZATION TIMER START**" Alarm Generate with Hooter			
When Im-108.01 Is Below Low System Tripped	"**IM-108.01 IS BELOW LOW SYSTEM TRIPPED**" Machine Gets Stopped with Hooter & Alarm			
WhenFt-108.01 Is Very Low Flow System Tripped	"**FT-108.01 IS VERY LOW FLOW SYSTEM TRIPPED**" Machine Gets Stopped with Hooter & Alarm			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When Sanitization Timer Over	"**SANITIZATION TIMER OVER**" Alarm Generate with Hooter			
When Sanitization Cycle Aborted	"**SANITIZATION CYCLE ABORTED**" Alarm Generate with Hooter			
When Sanitization Cycle Completed	"**SANITIZATION CYCLE COMPLETED**" Machine stop with Hooter & Alarm			
When Emergency Stop Pressed, System Tripped	"**EMERGENCY STOP PRESSED, SYSTEM TRIPPED**" Machine stop with Hooter & Alarm			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When Incoming Air To Panel Failed System Tripped	"**INCOMING AIR TO PANEL FAILED SYSTEM TRIPPED**" Machine stop with Hooter & Alarm			
WhenP-108.01/02 Tripped Due To Over Load	"**P-108.01/02 TRIPPED DUE TO OVER LOAD**" Machine stop with Hooter & Alarm			
When Incoming Power To Panel Failed, System Tripped	"**INCOMING POWER TO PANEL FAILED, SYSTEM TRIPPED**" Machine stop with Hooter & Alarm			
WhenRd-108.01 Bursted, System Tripped	"**RD-108.01 BRUSTED,SYSTEM TRIPPED**" Machine stop with Hooter & Alarm			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
WhenLt-108.01 Below Low Low, 108.01/02 Stopped	"**LT-108.01 BELOW LOW LOW, 108.01/02 STOPPED**" Machine stop with Hooter & Alarm			
WhenCt 108.01 High	"**CT 108.01 HIGH**" Alarm Generate with Hooter			
WhenCt 108.01 Is Very High System Tripped	"**CT 108.01 IS VERY HIGH SYSTEM TRIPPED**" Machine stop with Hooter & Alarm			
WhenToc-108.01 High (Action)	"**TOC-108.01 HIGH (ACTION)**" Alarm Generate with Hooter			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
WhenToc-108.01 Is Very High System Tripped	"**TOC-108.01 IS VERY HIGH SYSTEM TRIPPED**" Machine stop with Hooter & Alarm			
WhenFt-108.01 Low	"**FT-108.01 LOW**" Alarm Generate with Hooter			
When Sanitization Cycle Start	"**SANITIZATION CYCLE START**" Alarm Generate with Hooter			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When Incoming Power To Panel Resumes	"**INCOMING POWER TO PANEL RESUMES''** Alarm Generate.			
When IM-108.01 Low	"**IM-108.01 LOW** " Alarm Generate with Hooter			
WhenToc-108.01 High (Alert)	"**TOC-108.01 HIGH (ALERT)**" Alarm Generate with Hooter			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When Return Loop Temp Tt-108.02 Low	"**RETURN LOOP TEMP TT-108.02 LOW**" Alarm Generate with Hooter			
When Return Loop Temp Tt-108.02 High	"**RETURN LOOP TEMP TT-108.02 HIGH**" Alarm Generate with Hooter			
When Emergency Stop Released	"**EMERGENCY STOP RELEASED**" Alarm Generate.			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When TT 108.02 Is Above High High	"**TT 108.02 IS ABOVE HIGH HIGH**" Alarm Generate with Hooter			
When TT 108.02 Is Below Low Low	"**TT 108.02 IS BELOW LOW LOW**" Alarm Generate with Hooter			
When TT 108.01 Is Below Low Low	"**TT 108.01 IS BELOW LOW LOW**" Alarm Generate with Hooter			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
When TT 108.03 Is Above High High	"**TT 108.03 IS ABOVE HIGH HIGH**" Alarm Generate with Hooter			
When TT 108.03 Is Below Low Low	"**TT 108.03 IS BELOW LOW LOW**" Alarm Generate with Hooter			

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date : _____

Verified by (Engg.)   : _____   Sign & Date : _____

Reviewed by (QA)   : _____   Sign & Date : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

14.9   Verification of Power Failure Condition

Objective   :   To verify the power failure condition.

Tools Required   :   Not Applicable

Procedure   :   1.   Operate the system in run mode.

2.   Record the set parameters in the verification table.

3.   Shut down the power of the system for 5 min..

4.   Restart the power of the system.

5.   Record the set parameters in the verification table.

Acceptance   :   After restart the power, the set parameters shall remain unchanged.
Criteria

Verification Table:

Refer Attachment No.6				
Date & Time Before Power Loss:_____				
Date & Time After Power Recovery:_____				
Parameter Description	**Power Failure**		**Discrepancy? (Yes/No)**	**Done By Sign & Date**
	Parameter Value Before	**Parameter Value After**		
PW Set Parameter				
Return Loop Temp. TT-108.02 Low Low (ºC)				
Return Loop Temp. TT-108.02 Low (ºC)				
Return Loop Temp. TT-108.02 High (ºC)				
Return Loop Temp. TT-108.02 High High (ºC)				
IM-108.01 Low (W/m2)				

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameter Description	Power Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Conductivity CT-108.01 High (µS/cm)				
Return Loop FT-108.01 Low (LPH)				
Return Loop FT-108.01 High (LPH)				
TOC-108.01 High (Alert) (PPB)				
TOC-108.01 High Action (PPB)				
LT-108.01 LL				
LT-108.01 LH				
LT-108.01 HL				
LT-108.01 HH				
PW Sanitization Parameter				
PW Tank-TT 108.01 Low Low (°C)				
PW Tank-TT 108.01 Low (°C)				
PW Tank-TT 108.01 High (°C)				
Loop Return TT-108.02 Low Low (°C)				

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameter Description	Power Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Loop Return TT-108.02 Low (ᵒC)				
Loop Return TT-108.02 High (ᵒC)				
Loop Return TT-108.02 High High (ᵒC)				
Vent Filter TT-108.03 Low Low(ᵒC)				
Vent Filter TT-108.03 Low (ᵒC)				
Vent Filter TT-108.03 High (ᵒC)				
Vent Filter TT-108.03 High High (ᵒC)				
Sanitization Process				
Sanit Abort Time Set (SEC)				
Sanitization Frequency Set (HZ)				
Sanitization Tank Level Set (LTRS)				
Sanitization Time Set (MIN)				
PID Screen				
Gain				
Integral Time				
Derivative Time				

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameter Description	Power Failure				Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before		Parameter Value After			
PW Scalling-1 (AI)						
	Min.	Max.	Min.	Max		
TT-108.03 (°C)						
LT-108.01 (LTR)						
TT-108.01 (°C)						
IM-108.01 (W/m2)						
FT-108.01 (LPH)						
CT-108.01 (µS/cm)						
PW Scalling-2 (AI)						
TT-108.02 (°C)						
TOC-108.01(PPB)						
Analog Output						
VFD P-108.01/02 (HZ)						
PW Settable Timer						
IM-108.01 Low Time Set (SEC)						
CT-108.01 High Time Set(SEC)						
TOC-108.01 High Time Set(SEC)						
FT-108.01 Low Time Set(SEC)						

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date : _____

Verified by (Engg.)   : _____   Sign & Date : _____

Reviewed by (QA)   : _____   Sign & Date : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Verification of Communication Failure Condition:

Objective	:	To verify the communication failure condition.
Tools Required	:	Not Applicable
Procedure	:	1. Operate the system in run mode.
		2. Record the set parameters in the verification table.
		3. Disconnect the communication cable from the HMI for 5 min..
		4. Reconnect the communication cable to the HMI.
		5. Record the set parameters in the verification table.
Acceptance Criteria	:	After reconnect the communication cable, the set parameters shall remain unchanged.

Verification Table:

Refer Attachment No.7				
Date & Time Before Communication Failure:_____				
Date & Time After Communication Recovery:_____				
Parameter Description	**Communication Failure**		**Discrepancy ? (Yes/No)**	**Done By Sign & Date**
	Parameter Value Before	**Parameter Value After**		
PW Set Parameter				
Return Loop Temp. TT-108.02 Low Low (ᵒC)				
Return Loop Temp. TT-108.02 Low (ᵒC)				
Return Loop Temp. TT-108.02 High (ᵒC)				
Return Loop Temp. TT-108.02 High High (ᵒC)				
IM-108.01 Low (W/m2)				

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameter Description	Communication Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Conductivity CT-108.01 High (µS/cm)				
Return Loop FT-108.01 Low (LPH)				
Return Loop FT-108.01 High (LPH)				
TOC-108.01 High (Alert) (PPB)				
TOC-108.01High Action (PPB)				
LT-108.01 LL				
LT-108.01 LH				
LT-108.01 HL				
LT-108.01 HH				
PW Sanitization Parameter				
PW Tank-TT 108.01 Low Low (ºC)				
PW Tank-TT 108.01 Low (ºC)				
PW Tank-TT 108.01 High (ºC)				
Loop Return TT-108.02 Low Low (ºC)				

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameter Description	Communication Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Loop Return TT-108.02 Low (°C)				
Loop Return TT-108.02 High (°C)				
Loop Return TT-108.02 High High (°C)				
Vent Filter TT-108.03 Low Low(°C)				
Vent Filter TT-108.03 Low (°C)				
Vent Filter TT-108.03 High (°C)				
Vent Filter TT-108.03 High High (°C)				
Sanitization Process				
Sanit Abort Time Set (SEC)				
Sanitization Frequency Set (HZ)				
Sanitization Tank Level Set (LTRS)				
Sanitization Time Set (MIN)				
PID Screen				
Gain				
Integral Time				
Derivative Time				

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Parameter Description	Communication Failure				Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before		Parameter Value After			
PW Scalling-1 (AI)						
	Min.	Max.	Min.	Max		
TT-108.03 (ºC)						
LT-108.01 (LTR)						
TT-108.01 (ºC)						
IM-108.01 (W/m2)						
FT-108.01 (LPH)						
CT-108.01 (µS/cm)						
PW Scalling-2 (AI)						
TT-108.02 (ºC)						
TOC-108.01(PPB)						
Analog Output						
VFD P-108.01/02 (HZ)						
PW Settable Timer						
IM-108.01 Low Time Set (SEC)						
CT-108.01 High Time Set(SEC)						
TOC-108.01 High Time Set(SEC)						
FT-108.01 Low Time Set(SEC)						

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Verification of Control Loop Test:

Purpose	**:**	Verify the performance of integrated HMI system.
Scope	**:**	Check and record of an integrated control loop test.
Procedure	**:**	➢ Start the equipment in normally.
		➢ Login with higher level id and password.
		➢ Set require recipe for the test for process start
		➢ Start process and observe the set process parameters.
		➢ Record the reading of set process parameters until the completion of process.
		➢ If printing facility available, attached the printout of whole integrated control loop test.
Acceptance Criteria	**:**	HMI system should able to control the set process parameter within the specified limit

Verification Table:Verification of Control Loop Test

Refer Attachment No.8				
Parameter	**Specified**	**Actual Result**	**Discrepancy? (Yes/No)**	**Done By Sign & Date**
PW Set Parameter				
Return Loop Temp. TT-108.02 Low Low (ºC)	0.0 to 150.0			
Return Loop Temp. TT-108.02 Low (ºC)	0.0 to 150.0			
Return Loop Temp. TT-108.02 High (ºC)	0.0 to 150.0			
Return Loop Temp. TT-108.02 High High (ºC)	0.0 to 150.0			
IM-108.01 Low (W/m2)	0 to 100			
Conductivity CT-108.01 High (µS/cm)	0.00 to 10.00			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Refer Attachment No.8				
Parameter	Specified	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
Return Loop FT-108.01 Low (LPH)	0.0 to 10000.0			
Return Loop FT-108.01 High (LPH)	0.0 to 10000.0			
TOC-108.01 High (Alert) (PPB)	0.0 to 500.0			
TOC-108.01 High Action (PPB)	0.0 to 500.0			
LT-108.01 LL	0 to 5000			
LT-108.01 LH	0 to 5000			
LT-108.01 HL	0 to 5000			
LT-108.01 HH	0 to 5000			
PW Sanitization Parameter				
PW Tank-TT 108.01 Low Low (°C)	0.0 to 150.0			
PW Tank-TT 108.01 Low (°C)	0.0 to 150.0			
PW Tank-TT 108.01 High (°C)	0.0 to 150.0			
Loop Return TT-108.02 Low Low (°C)	0.0 to 150.0			
Loop Return TT-108.02 Low (°C)	0.0 to 150.0			
Loop Return TT-108.02 High (°C)	0.0 to 150.0			
Loop Return TT-108.02 High High (°C)	0.0 to 150.0			
Vent Filter TT-108.03 Low Low(°C)	0.0 to 150.0			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Refer Attachment No.8				
Parameter	**Specified**	**Actual Result**	**Discrepancy? (Yes/No)**	**Done By Sign & Date**
Vent Filter TT-108.03 Low (°C)	0.0 to 150.0			
Vent Filter TT-108.03 High (°C)	0.0 to 150.0			
Vent Filter TT-108.03 High High (°C)	0.0 to 150.0			
Sanitization Process				
Sanit Abort Time Set (SEC)	0 to 9999			
Sanitization Frequency Set (HZ)	0.00 to 60.00			
Sanitization Tank Level Set (LTRS)	0 to 5000			
Sanitization Time Set (MIN)	0 to 999			
PID Screen				
Gain	0 to 99			
Integral Time	0 to 99			
Derivative Time	0 to 99			
PW Settable Timer				
IM-108.01 Low Time Set (SEC)	0 to 999			
CT-108.01 High Time Set(SEC)	0 to 999			
TOC-108.01 High Time Set(SEC)	0 to 999			
FT-108.01 Low Time Set(SEC)	0 to 999			

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

Remarks:

_____

_____

Meet the acceptance Criteria [   ] Yes   [   ] No

Checked by   : _____   Sign & Date   : _____

Verified by (Engg.)   : _____   Sign & Date   : _____

Reviewed by (QA)   : _____   Sign & Date   : _____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

15. OPERATIONAL QUALIFICATION TEST STATUS

The operational qualification test status is as per below mentioned table.

Test Description	Status (Pass / Fail)	Discrepancy? (Yes/No)
Verification of Field Instruments Calibration Details		
Verification of PLC LED's.		
Verification of PLC Input and Output.		
Verification of Password Security		
Verification of User Level & Rights		
Verification of HMI Screens.		
Verification of Set Parameter Boundary Condition.		
Verification of Alarms and Interlocks.		
Verification of Power Failure Condition.		
Verification of Communication Failure Condition.		
Verification of Control Loop Test		

16. DISCREPANCIES HANDLING DURING PLC QUALIFICATION:

- In case of discrepancy observed during qualification, document in the defined column in each table and document the details of the observation in the discrepancy log sheet.
- Inform to production, engineering and quality assurance about discrepancy.
- Investigate the discrepancy and ensure the possible impact.
- If discrepancy does not have potential to impact on operation as well as performance of the system, close the discrepancy with proper justification.
- The production, engineering and QA will decide whether discrepancy is acceptable or not.
- If discrepancy is acceptable, provide conclusion and recommendation if any into respective column.

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

17. DISCREPANCY AND CORRECTIVE ACTION FORM:

Protocol Reference	
Discrepancy Number	

DISCREPANCY

Describe the Discrepancy	
Reported by	Date

CORRECTIVE ACTION

Describe corrective action taken (Attach additional sheets if necessary)	
Reported by	Date

DISPOSITION ACTION

Acceptable? Yes No	
Discussion	
Approved by	Date

COMPLETION

Completed by	Date

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

18. ABBREVIATION:

Abbreviations	Description
GMP	Good Manufacturing Practices
HMI	Human Machine Interface
PLC	Programable Logic Controller
SRS	System Requirement and Specification
IQ	Installation Qualification
OQ	Operation Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
NA	Not Applicable
ICH	International Conference of Harmonization
mA	mili Ampere
ACV	Alternate Current Voltage
DCV	Direct Current Voltage
RH	Relative Humidity

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

19. ATTACHMENT SUMMARY:

Attachment No.	Description

20. OPERATIONAL QUALIFICATION SUMMARY & CONCLUSION:

Compiled by: _____ **Date:**_____

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER DISTRIBUTION LOOP SYSTEM

21. POST APPROVALS

The signature listed below indicates the post approval of this operational qualification. This approval is joint responsibility of listed functional areas.

Function	Name	Department	Designation	Signature & Date
……….…………..				
Executed by		Engineering		
…………………				
Reviewed by		Engineering		
Reviewed by		Production		
Reviewed by		Quality Assurance		
……………………				
Approved by		Quality Assurance		