



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

**OPERATIONAL QUALIFICATION FOR  
FOR PLC SYSTEM OF  
PURIFIED WATER GENERATION SYSTEM**

<b>Equipment Name</b>	Purified Water Generation System
<b>Equipment ID</b>	
<b>System Location</b>	Water System
<b>Effective Date</b>	



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

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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
<b>Instrumentation and Control Solutions, Indore</b>				
<b>Prepared by</b>		<b>Engineering</b>		
.....				
<b>Reviewed by</b>		<b>Engineering</b>		
<b>Reviewed by</b>		<b>Production</b>		
<b>Reviewed by</b>		<b>Quality Assurance</b>		
.....				
<b>Approved by</b>		<b>Quality Assurance</b>		



## **OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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 Generation System installed, and define the operational qualification requirements and acceptance criteria for the Programmable logic controller (PLC) and HMI Based system of Purified Water Generation 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 Generation System was functioning properly.

### **3. SCOPE:**

This document is applicable to Programmable logic controller (PLC) and HMI Based system of Purified Water Generation 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 Generation System is installed in accordance with the guidelines laid down by the manufacturer of the system.

### **4. SYSTEM DESCRIPTION:**

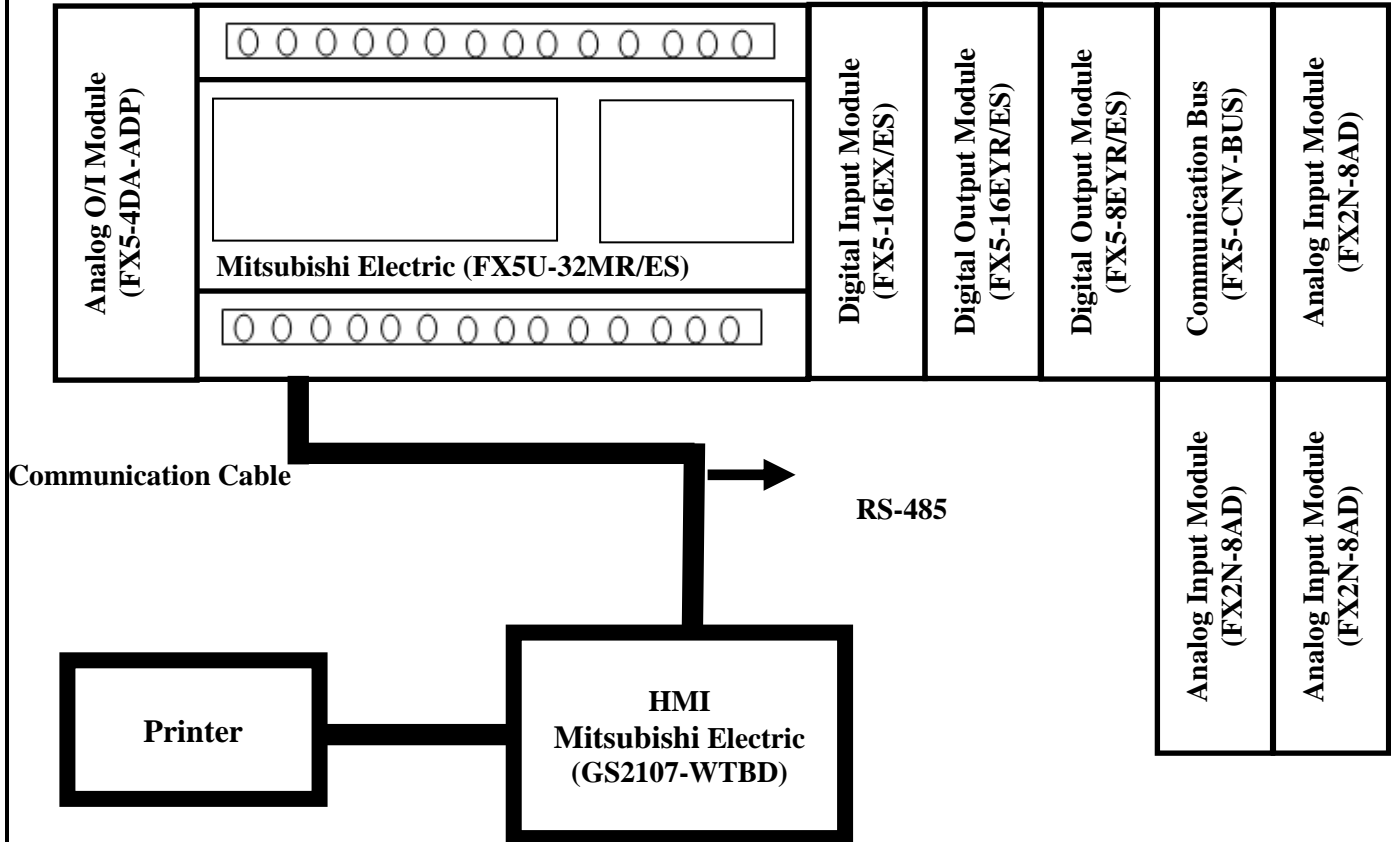
Equipment Name	:	Purified Water Generation System
Supplier / Manufacturer	:	.....
Equipment ID .No.	:	.....
Location	:	Water System



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**5. CONTROL SYSTEM SCHEMATIC DIAGRAM:**

The PLC System schematic diagram for the “Purified Water Generation System” automation is given below:





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**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.



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**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.

<b>Department</b>	<b>Responsibilities</b>
Validation Agency (Instrumentation and Control Solutions)	<ul style="list-style-type: none"><li>➤ To collect the necessary data for operational qualification activities.</li><li>➤ To prepare and execute the operational qualification in coordination with engineering, validation and quality assurance team.</li><li>➤ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle.</li><li>➤ To submit operational qualification for approval.</li></ul>
Engineering (M/s. ....)	<ul style="list-style-type: none"><li>➤ To provide the necessary data for operational qualification activities.</li><li>➤ To review and approve the operational qualification.</li></ul>
Production (M/s. ....)	<ul style="list-style-type: none"><li>➤ To provide the necessary data for operational qualification activities.</li><li>➤ To review and approve the operational qualification.</li></ul>
Quality Assurance (M/s. ....)	<ul style="list-style-type: none"><li>➤ To review and approve the operational qualification.</li></ul>



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

**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.





## **OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

### **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 Generation 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 Generation 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.



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**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 GENERATION 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						
S.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 : \_\_\_\_\_ Sign & Date : \_\_\_\_\_  
Reviewed by : \_\_\_\_\_ Sign & Date : \_\_\_\_\_



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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 Criteria : LED indication shall match with specified results in verification table.

**Verification Table:**

Description	LED Indication	Observation	Discrepancy? (Yes/No)	Done By Sign & Date
<b>PLC</b>				
PWR	ON			
ERR	OFF			
P. RUN	ON			
BAT	OFF			

Remarks:

\_\_\_\_\_

\_\_\_\_\_

Meet the acceptance Criteria [  ] Yes [  ] No

Checked by (....) : \_\_\_\_\_ Sign & Date : \_\_\_\_\_

Verified by (.....) : \_\_\_\_\_ Sign & Date : \_\_\_\_\_

Reviewed by (QA) : \_\_\_\_\_ Sign & Date : \_\_\_\_\_



## **OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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 GENERATION SYSTEM

### 14.3.1 Verification Table: Digital Input:

PLC Channel	IO Description	Specified LED Status		Observation LED Status		Discrepancy? (Yes/No)	Done By Sign & Date
<b>Module FX5U-32MR/ES</b>							
X0	EMG. STOP	ON	OFF				
X1	HOOPER ACK	ON	OFF				
X2	POWER FAIL	ON	OFF				
X3	ROFP-201 RUN FEEDBACK	ON	OFF				
X4	ROHP-201 RUN FEEDBACK	ON	OFF				
X5	ROHP-202 RUN FEEDBACK	ON	OFF				
X6	UFFP-201 RUN FEEDBACK	ON	OFF				
X7	EDI-201 RUN FEEDBACK	ON	OFF				
X10	AIR PRESSURE LOW	ON	OFF				
X11	LLS-201-LOW	ON	OFF				
X12	LLS-202-LOW	ON	OFF				
X13	LLS-203-LOW	ON	OFF				
X14	LPS-201	ON	OFF				
X15	LPS-202	ON	OFF				
X16	LPS-203	ON	OFF				
X17	RM-203-LOW	ON	OFF				
<b>Module FX5-16EX/ES</b>							
X0	RM-204-LOW	ON	OFF				
X1	PS-201-HIGH	ON	OFF				
X2	LS-201-HH	ON	OFF				
X3	LS-201-H	ON	OFF				
X4	LS-201-L	ON	OFF				
X5	LS-201-LL	ON	OFF				
X6	DPIS-201	ON	OFF				
X7	DPIS-202	ON	OFF				
X0	DPIS-203	ON	OFF				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

PLC Channel	IO Description	Specified LED Status		Observation LED Status		Discrepancy? (Yes/No)	Done By Sign & Date
		ON	OFF				
X1	LEVEL HEALTHY SIGNAL	ON	OFF				
X2	LS-202-HH	NA	NA				
X3	LS-202-H	NA	NA				
X4	LS-202-L	NA	NA				
X5	LS-202-LL	NA	NA				
X6	SPARE	NA	NA				
X7	SPARE	NA	NA				



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

**14.3.2 Verification Table: Digital Output**

PLC Channel	IO Description	Specified LED Status		Observation LED Status	Discrepancy? (Yes/No)	Done By Sign & Date
<b>Module FX5U-32MR/ES</b>						
Y0	FAULT LAMP	ON	OFF			
Y1	VALVE AV-201	ON	OFF			
Y2	VALVE AV-202	ON	OFF			
Y3	VALVE AV-203	ON	OFF			
Y4	VALVE AV-204	ON	OFF			
Y5	VALVE AV-205	ON	OFF			
Y6	VALVE AV-206	ON	OFF			
Y7	VALVE AV-207	ON	OFF			
Y10	VALVE AV-208	ON	OFF			
Y11	VALVE AV-209	ON	OFF			
Y12	VALVE AV-210	ON	OFF			
Y13	VALVE AV-211	ON	OFF			
Y14	VALVE AV-212	ON	OFF			
Y15	VALVE AV-213	ON	OFF			
Y16	VALVE ADV-201	ON	OFF			
Y17	VALVE ADV-202	ON	OFF			
<b>Module FX5-16EY/ES</b>						
Y0	VALVE FDV-201	ON	OFF			
Y1	VALVE FDV-202	ON	OFF			
Y2	VALVE AV-214	NA	NA			
Y3	VALVE AV-215	NA	NA			
Y4	VALVE AV-216	NA	NA			
Y5	HOOTER	ON	OFF			
Y6	DP-201	ON	OFF			
Y7	DP-202	ON	OFF			
Y0	DP-203	ON	OFF			
Y1	EVF-201	ON	OFF			
Y2	ROFP-201	ON	OFF			





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PLC Channel	IO Description	Specified LED Status		Observation LED Status		Discrepancy? (Yes/No)	Done By Sign & Date
		ON	OFF				
Y3	ROHP-201	ON	OFF				
Y4	ROHP-202	ON	OFF				
Y5	UFFP-201	ON	OFF				
Y6	EDI-201	ON	OFF				
Y7	SPARE	NA	NA				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

PLC Address	Details	Input Signal	Expected Process Reading	Actual Process Reading	Meets acceptance criteria		Sign. & date
					Yes	No	
<b>Module FX2N-8AD (M3)</b>							
IN1	PH-201	4.000 mA	0.00 PH		( )	( )	
		12.000 mA	7.00 PH		( )	( )	
		20.000 mA	14.00 PH		( )	( )	
IN2	ORP-201	4.000 mA	-1500mV		( )	( )	
		12.000 mA	0000 mV		( )	( )	
		20.000 mA	1500 mV		( )	( )	
IN3	CT-201	4.000 mA	0.0 uS/cm		( )	( )	
		12.000 mA	100.0 uS/cm		( )	( )	
		20.000 mA	200.0 uS/cm		( )	( )	
IN4	CT-202	4.000 mA	0.0 uS/cm		( )	( )	
		12.000 mA	50.0 uS/cm		( )	( )	
		20.000 mA	100.0 uS/cm		( )	( )	
IN5	CT-203	4.000 mA	0.00uS/cm		( )	( )	
		12.000 mA	5.00uS/cm		( )	( )	
		20.000 mA	10.00 uS/cm		( )	( )	
IN6	PH-202	4.000 mA	0.00 PH		( )	( )	
		12.000 mA	7.00 PH		( )	( )	
		20.000 mA	14.00 PH		( )	( )	
IN7	TT-201	4.000 mA	000.0 DEG.C		( )	( )	
		12.000 mA	100.0 DEG.C		( )	( )	
		20.000 mA	200.0 DEG.C		( )	( )	
IN8	TT-202	4.000 mA	000.0 DEG.C		( )	( )	
		12.000 mA	100.0 DEG.C		( )	( )	
		20.000 mA	200.0 DEG.C		( )	( )	



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**14.3.3 Verification Table: Analog Input**

PLC Address	Details	Input Signal	Expected Process Reading	Actual Process Reading	Meets acceptance criteria		Sign. & Date
					Yes	No	
<b>Module FX2N-8AD (M4)</b>							
IN1	TT-203	4.000 mA	000.0 DEG.C		( )	( )	
		12.000 mA	100.0 DEG.C		( )	( )	
		20.000 mA	200.0 DEG.C		( )	( )	
IN2	TT-204	4.000 mA	000.0 DEG.C		( )	( )	
		12.000 mA	100.0 DEG.C		( )	( )	
		20.000 mA	200.0 DEG.C		( )	( )	
IN3	FT-201	4.000 mA	0.00 m3/Hr		( )	( )	
		12.000 mA	2.50 m3/Hr		( )	( )	
		20.000 mA	5.00 m3/Hr		( )	( )	
IN4	FT-202	4.000 mA	0.00 m3/Hr		( )	( )	
		12.000 mA	2.50 m3/Hr		( )	( )	
		20.000 mA	5.00 m3/Hr		( )	( )	
IN5	FT-203	4.000 mA	0.00 m3/Hr		( )	( )	
		12.000 mA	2.50 m3/Hr		( )	( )	
		20.000 mA	5.00 m3/Hr		( )	( )	
IN6	FT-204	4.000 mA	0.00 m3/Hr		( )	( )	
		12.000 mA	2.50 m3/Hr		( )	( )	
		20.000 mA	5.00 m3/Hr		( )	( )	
IN7	FT-205	4.000 mA	0.00 m3/Hr		( )	( )	
		12.000 mA	2.05 m3/Hr		( )	( )	
		20.000 mA	4.10 m3/Hr		( )	( )	
IN8	FT-206	4.000 mA	0.00 m3/Hr		( )	( )	
		12.000 mA	2.50 m3/Hr		( )	( )	
		20.000 mA	5.00 m3/Hr		( )	( )	



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PLC Address	Details	Input Signal	Expected Process Reading	Actual Process Reading	Meets acceptance criteria		Sign. & date
					Yes	No	
<b>Module FX2N-8AD (M5)</b>							
IN1	PT-201	4.000 mA	00.00 bar		( )	( )	
		12.000 mA	20.00 bar		( )	( )	
		20.000 mA	40.00 bar		( )	( )	
IN2	PT-202	4.000 mA	00.00 bar		( )	( )	
		12.000 mA	20.00 bar		( )	( )	
		20.000 mA	40.00 bar		( )	( )	
IN3	SPARE	NA	NA		( )	( )	
IN4	SPARE	NA	NA		( )	( )	
IN5	SPARE	NA	NA		( )	( )	
IN6	SPARE	NA	NA		( )	( )	
IN7	SPARE	NA	NA		( )	( )	
IN8	SPARE	NA	NA		( )	( )	



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

PLC Address	Details	Set value from HMI	Output Signal	Actual Reading	Meets acceptance criteria		Sign. & date
					Yes	No	
<b>Module FX5-4DA-ADP</b>							
OUT1	PIDV-201	000.0 %	4.000 mA		( )	( )	
		050.0 %	12.000 mA		( )	( )	
		100.0 %	20.000 mA		( )	( )	
OUT2	PIDV-202	000.0 %	4.000 mA		( )	( )	
		050.0 %	12.000 mA		( )	( )	
		100.0 %	20.000 mA		( )	( )	
OUT3	DP-202	000.0 %	4.000 mA		( )	( )	
		050.0 %	12.000 mA		( )	( )	
		100.0 %	20.000 mA		( )	( )	
OUT4	DP-203	000.0 %	4.000 mA		( )	( )	
		050.0 %	12.000 mA		( )	( )	
		100.0 %	20.000 mA		( )	( )	



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

**14.3.4 Verification Table: Analog Output Module**

**Remarks:**

---

---

Meet the acceptance Criteria [  ] Yes [  ] No

Checked by (.....) : \_\_\_\_\_ Sign & Date : \_\_\_\_\_

Verified by (.....Engg.) : \_\_\_\_\_ Sign & Date : \_\_\_\_\_

Reviewed by (..... QA) : \_\_\_\_\_ Sign & Date : \_\_\_\_\_



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### 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 : All the test result shall match with specified result.

Criteria

#### 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 : \_\_\_\_\_



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### 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Manufacturing Parameters Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Manufacturing Parameters Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Digital Input Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Digital Output Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Mode Selection Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Print Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Parameters Screen-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Parameters Screen-1 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Parameters Screen-2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Parameters Screen-2 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Refer Attachment No.3					





**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

Right /Screen	Operator Level	Supervisor Level	Manager Level	Admin Level	Done By Sign &Date
<b>Page No.</b>					
RO Parameters Screen-3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Parameters Screen-3 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Post UF Parameters Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Post UF Parameters Screen Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Mimic Screen-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Mimic Screen-1 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Mimic Screen-2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Mimic Screen-2 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Mimic Screen-3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RO Mimic Screen-3 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Post UF Mimic Screen-1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Post UF Mimic Screen-1 Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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 GENERATION 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

S.No.	HMI Screen	Refer Attachment No.4 Screen No.	Discrepancy? (Yes/No)	Done By Sign & Date
1	Welcome Screen			
2	Manufacturing Parameters Screen			
3	Digital Input Screen			
4	Digital Output Screen			
5	Mode Selection Screen			
6	Print Screen			
7	RO Parameters Screen-1			
8	RO Parameters Screen-2			
9	RO Parameters Screen-3			
10	Post UF Parameters Screen			
11	RO Mimic Screen-1			
12	RO Mimic Screen-2			
13	RO Mimic Screen-3			
14	Post UF Mimic Screen-1			



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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 GENERATION 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 GENERATION 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
<b>Manufacturing Parameters</b>											
PH-201 FS (PH)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
ORP-201 FS (mV)	-32768 to 32767		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
ORP-201 ZFS (mV)	-32768 to 32767		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-201 FS (uS/cm)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-202 FS (uS/cm)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-203 FS (uS/cm)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-201 FS (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-202 FS (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-203 FS (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-204 FS (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
FT-201 FS (m3/Hr.)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
FT-202 FS (m3/Hr)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
FT-203 FS (m3/Hr)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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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	
FT-204 FS (m3/Hr)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
FT-205 FS (m3/Hr)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
FT-206 FS (m3/Hr)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
PT-201 FS (bar)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
PT-202 FS (bar)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
PH-202 FS (PH)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
<b>P Factor</b>												
DP-202	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
DP-203	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
PIDV-201	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
PIDV-202	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
<b>I Factor</b>												
DP-202	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
<b>I Factor Continue</b>												
DP-203	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			
PIDV-201	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>			



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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
PIDV-202	-999 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>Manufacturing Parameters</b>											
Temperature Hysteresis	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Flow Hysteresis	-99.9 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Set Parameters Screen-1</b>											
RO 1 Concentrate Flushing Time (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
RO 1 Permeate Reject Time (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
RO 2 Concentrate Flushing Time (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
RO 2 Permeate Reject Time (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
EDI-201 OFF Delay Time (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Set Parameters Continue</b>											
RO Flushing Delay Time (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
RO Idle Time (Min)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
ORP-201 HHSP (mV)	0 to 1500		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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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
ORP-201 CSP (mV)	-32768 to 32767		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
ORP-201 HSP (mV)	0 to 300		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
ORP 201 Prolong Delay Timer (Secs)	0 to 300		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-201 HHSP (PH)	9.00 to 14.00		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-201 HSP (PH)	7.00 to 9.00		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-201 CSP (PH)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-201 LSP (PH)	6.00 to 8.00		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-201 LLSP (PH)	0.00 to 7.00		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-201 Prolong Delay Timer (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		





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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
<b>RO Set Parameters Continue</b>											
PH-201 Prolong Delay Timer (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Set Parameters Screen-2</b>											
CT-201 HHSP (Us/cm)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-201 HSP (Us/cm)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-201 Prolong Delay Timer (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-202 HHSP (Us/cm)	18.0 to 100.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-202 HSP (Us/cm)	0.0 to 20.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-202 Prolong Delay Timer (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PT-201 HSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PT-202 HSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-203 HHSP (Us/cm)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-203 HSP (Us/cm)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
CT-203 Prolong delay timer (Sec)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Set Parameters Screen-2 Continue</b>											
FT-202 CSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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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
FT-202 LSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
FT-203 CSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
FT-203 LSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-202 HSP (DEG.C)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PH-202 LSP (DEG.C)	0.00 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Set Parameters Screen-3</b>											
TT-203 Heat SP (DEG.C)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-203 Cool SP (DEG.C)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-201 HSP (DEG.C)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-201 CSP (DEG.C)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-201 LSP (DEG.C)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Sanitization Hold Timer (Min)	1 to 120		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Set Parameters Screen-3 Continue</b>											
Commulative Timer (Min)	60 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
AV-205 Drain Timer (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



# PHARMA DEVILS

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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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
TT-202 CSP (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-202 HSP (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PT-201 HSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PT-202 HSP (m3/Hr)	-99.99 to 99.99		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>Post UF Parameters</b>											
UF-201 Start-up-sequence Flushing Cycle (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
UF-201 Service Cycle (Mins)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
UF-201 Fast Flush (Secs)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
UF-201 Prolong Delay Time (Min)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
UF-201 Idle Time (Min)	0 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>Post UF Parameters Continue</b>											
TT-203 Heat SP (DEG.C)	0.0 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-203 Cool SP (DEG.C)	0.0 to 90.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-204 HSP (DEG.C)	0.0 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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
TT-204 CSP (DEG.C)	0.0 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-204 LSP (DEG.C)	-999.9 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-204 CSP (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
TT-204 HSP (DEG.C)	0.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Sanitization Hold Timer (Min)	1 to 120		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Cumm Hold Timer (Min)	60 to 999		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Mimic Screen-1</b>											
DP-203 Set%	000.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
DP-202 Set%	000.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Mimic Screen-2</b>											
ROHP-201 Set HZ	00.0 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PIDF-201 Set%	000.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>RO Mimic Screen-3</b>											
ROHP-202 Set HZ	00.0 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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
PIDF-202 Set%	000.0 to 999.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Post UF Mimic Screen											
UFFP-201 Set HZ	00.0 to 99.9		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		

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 : \_\_\_\_\_

### 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.



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

### Verification Table:

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When Air Pressure Is Low	<b>“AIR PRESSURE LOW”</b> Machine Gets Tripped with Hooter & Alarm			
When Emergency Switch Pressed	<b>“EMERGENCY SWITCH PRESSED”</b> Machine Gets Stopped with Hooter & Alarm			
When Power Is Failure	<b>“POWER FAILURE”</b> Machine Gets Stopped with Hooter & Alarm			
When Pump Rofp-201 Is Electrically Tripped	<b>“PUMP ROFP-201 IS ELECTRICALLY TRIPPED”</b> Machine Gets Stopped with Hooter & Alarm			
When Pump Rohp-201 Is Electrically Tripped	<b>“PUMP ROHP-201 IS ELECTRICALLY TRIPPED”</b> Machine Gets Tripped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When Pump Rohp-202 Is Electrically Tripped	<b>“PUMP ROHP-202 IS ELECTRICALLY TRIPPED”</b> Machine Gets Tripped with Hooter & Alarm			
When LS-201 is Low-Low	<b>“LS-201 Low-Low”</b> Machine Gets Tripped with Hooter & Alarm			
When SMBS Doing Tank Level LLS-203 is Low	<b>“SMBS DOING TANK LEVEL LLS-203 LOW ”</b> Machine Gets Tripped with Hooter & Alarm			
When ADS Doing Tank Level LLS-201 is Low	<b>“ADS DOING TANK LEVEL LLS-201 LOW”</b> Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When pH Doing Tank Level LLS-202 is Low	<b>“pH DOING TANK LEVEL LLS-202 LOW”</b> Machine Gets Tripped with Hooter & Alarm			
When pH -201 is low	<b>“pH -201 low”</b> Machine Gets Tripped with Hooter & Alarm			
When pH-201 is Low Low	<b>“pH-201 LOW LOW”</b> Alarm Occurs with Hooter			
When pH-201 is Prolong Delay Timer Over	<b>“pH-201 PROLONG DELAY TIMER OVER”</b> Machine Gets Tripped with Hooter & Alarm			





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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When pH-201 is High	<b>“pH-201 HIGH”</b> Alarm Occurs with Hooter & Discharging Does not Starts or Gets Stopped			
When pH-201 is High High	<b>“pH-201 HIGH HIGH”</b> Alarm Occurs with Hooter & Discharging Does not Starts or Gets Stopped			
When ORP-201 is High	<b>“ORP-201 HIGH”</b> Machine Gets Tripped with Hooter & Alarm			
When ORP-201 is High High	<b>“ORP-201 HIGH HIGH”</b> Machine Gets Tripped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When ORP-201 is Prolong Delay Timer Over	<b>“ORP-201 PROLONG DELAY TIMER OVER”</b> Hooter & Alarm and Discharge port won't Open			
When FT-202 is Low	<b>“FT-202 LOW ”</b> Machine Gets Stopped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When LPS 201 is Low	<b>“LPS-201 LOW ”</b> Machine Gets Tripped with Hooter & Alarm			
When PT-201 is High	<b>“PT-201 HIGH ”</b> Machine Gets Tripped with Hooter & Alarm			
When CT-201 is High	<b>“CT-201 HIGH ”</b> Machine Gets Tripped with Hooter & Alarm			
When CT-201 is High-High	<b>“CT-201 HIGH-HIGH ”</b> Machine Gets Stopped with Hooter & Alarm			
When CT-201 is Prolong Delay Timer Over	<b>“CT-201 PROLONG DELAY TIMER OVER”</b> Machine Gets Stopped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When FT-203 is Low	<b>"FT-203 LOW"</b> Machine Gets Stopped with Hooter & Alarm			
When LPS-202 is Low	<b>"LPS-202 LOW"</b> Machine Gets Tripped with Hooter & Alarm			
When PT-202 is High	<b>"PT-202 HIGH"</b> Machine Gets Tripped with Hooter & Alarm			
When CT-202 is High	<b>"CT-202 HIGH"</b> Machine Gets Tripped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When CT-202 is High-High	<b>“CT-202 HIGH-HIGH”</b> Machine Gets Tripped with Hooter & Alarm			
When CT-202 is Prolong Delay Timer Over	<b>“CT-202 PROLONG DELAY TIMER OVER”</b> Hooter & Alarm			
When LPS-203 is Low	<b>“LPS-203 LOW”</b> Machine Gets Tripped with Hooter & Alarm			
When EDI-201 Off Delay Timer Over(LPS-203 is Low)	<b>“EDI-201 OFF DELAY TIMER OVER(LPS-203 LOW)”</b> Machine Gets Tripped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When RM-203 is Low	<b>“RM-203 LOW”</b> Alarm Occurs with Hooter			
When EDI-201 is Electrically Tripped	<b>“EDI-201 ELECTRICALLY TRIPPED”</b> Alarm Occurs with Hooter & Discharging Does not Starts or Gets Stopped			
When EDI-201 Off Delay Timer Over(Rm-203 is Low)	<b>“EDI-201 OFF DELAY TIMER OVER(RM-203 LOW)”</b> Machine Gets Tripped with Hooter & Alarm			
When RM-204 is Low	<b>“RM-204 LOW”</b> Alarm Occurs with Hooter & Discharging Does not Starts or Gets Stopped			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When EDI-201 Off Delay Timer Over(RM-204 is Low)	<b>“EDI-201 OFF DELAY TIMER OVER(RM-204 LOW)”</b> Machine Gets Tripped with Hooter & Alarm			
When CT-203 is High	<b>“CT-203 HIGH”</b> Machine Gets Tripped with Hooter & Alarm			
When CT-203 is High-High	<b>“CT-203 HIGH-HIGH”</b> Hooter & Alarm and Discharge port won't Open			
When CT-203 Prolong Delay Timer Over	<b>“CT-203 PROLONG DELAY TIMER OVER”</b> Machine Gets Stopped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When pH-202 is Low	<b>“pH-202 LOW”</b> Machine Gets Stopped with Hooter & Alarm			
When DPIS-201 is High	<b>“DPIS-201 HIGH”</b> Machine Gets Stopped with Hooter & Alarm			
When DPIS-202 is High	<b>“DPIS-202 HIGH”</b> Machine Gets Tripped with Hooter & Alarm			
When DPIS-203 is High	<b>“DPIS-203 HIGH”</b> Machine Gets Stopped with Hooter & Alarm			
When LS-202 is High-High	<b>“LS-202 HIGH-HIGH”</b> Machine Gets Stopped with Hooter & Alarm			





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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When LS-202 is Low-Low	<b>"LS-202 LOW-LOW"</b> Machine Gets Stopped with Hooter & Alarm			
When TT-202 is High	<b>"TT-202 HIGH"</b> Machine Gets Tripped with Hooter & Alarm			
When Pump UFFP-201 Is Electrically Tripped	<b>"PUMP UFFP-201 IS ELECTRICALLY TRIPPED"</b> Machine Gets Tripped with Hooter & Alarm			
When PS-201 is High	<b>"PS-201 HIGH"</b> Machine Gets Tripped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When No PWD Demand Signal	<b>“NO PWD DEMAND SIGNAL”</b> Machine Gets Tripped with Hooter & Alarm			
When PWG Sanitization Hold Timer Over	<b>“PWG SANITIZATION HOLD TIMER OVER”</b> Hooter & Alarm			
When PWG Sanitization Cycle Over	<b>“PWG SANITIZATION CYCLE OVER”</b> Machine Gets Tripped with Hooter & Alarm			
When Sanitization Temperature is Low	<b>“SANITIZATION TEMPERATURE LOW”</b> Machine Gets Tripped with Hooter & Alarm			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When PWG Cumulative Timer Over	<b>“PWG CUMULATIVE TIMER OVER”</b> Alarm Occurs with Hooter			
When PWG Sanitization Aborted	<b>“PWGSANITIZATION ABORTED”</b> Machine Gets Tripped with Hooter & Alarm			
When Temperature at TT-201 High	<b>“TEMPERATURE At TT-201 HIGH”</b> Alarm Occurs with Hooter & Discharging Does not Starts or Gets Stopped			
When UF-201 Sanitization Hold Timer Over	<b>“UF-201 SANITIZATION HOLD TIMER OVER”</b> Alarm Occurs with Hooter & Discharging Does not Starts or Gets Stopped			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When UF-201 Sanitization Cycle Over	<b>“UF-201 SANITIZATION CYCLE OVER”</b> Machine Gets Tripped with Hooter & Alarm			
When UF-201 Cumulative Timer Over	<b>“UF-201 CUMULATIVE TIMER OVER”</b> Machine Gets Tripped with Hooter & Alarm			
When Sanitization is Aborted	<b>“SANITIZATION ABORTED”</b> Hooter & Alarm and Discharge port won't Open			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Condition	Expected Result	Actual Result	Discrepancy ? (Yes/No)	Done By Sign & Date
When Temperature at TT-204 is High	<b>“TEMPERATURE At TT-204 HIGH”</b> Machine Gets Stopped with Hooter & Alarm			

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

#### 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		
Manufacturing Parameters				
PH-201 FS (PH)				
ORP-201 FS (mV)				
ORP-201 ZFS (mV)				
CT-201 FS (uS/cm)				
CT-202 FS (uS/cm)				
CT-203 FS (uS/cm)				
TT-201 FS (DEG.C)				
TT-202 FS (DEG.C)				
TT-203 FS (DEG.C)				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Power Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Manufacturing Parameters Continues				
TT-204 FS (DEG.C)				
FT-201 FS (m3/Hr)				
FT-202 FS (m3/Hr)				
FT-203 FS (m3/Hr)				
FT-204 FS (m3/Hr)				
FT-205 FS (m3/Hr)				
FT-206 FS (m3/Hr)				
PT-201 FS (bar)				
PT-202 FS (bar)				
PH-202 FS (PH)				
P Factor				
DP-202				
DP-203				
PIDV-201				
PIDV-202				
I Factor				
DP-202				
DP-203				
PIDV-201				
PIDV-202				
Manufacturing Parameters				
Temperature Hysteresis				
Flow Hysteresis				
RO Set Parameters Screen-1				
RO 1 Concentrate Flushing Time (Secs)				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Power Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
RO Set Parameters Screen-1 Continue				
RO 1 Permeate Reject Time (Secs)				
RO 2 Concentrate Flushing Time (Secs)				
RO 2 Permeate Reject Time (Secs)				
EDI-201 OFF Delay Time (Secs)				
RO Flushing Delay Time (Secs)				
RO Idle Time (Min)				
ORP-201 HHSP (mV)				
ORP-201 CSP (mV)				
ORP-201 HSP (mV)				
ORP 201 Prolong Delay Timer (Secs)				
PH-201 HHSP (PH)				
PH-201 HSP (PH)				
PH-201 CSP (PH)				
PH-201 LSP (PH)				
PH-201 LLSP (PH)				
PH-201 Prolong Delay Timer (Secs)				
PH-201 Prolong Delay Timer (Secs)				
RO Set Parameters Screen-2				
CT-201 HHSP (Us/cm)				
CT-201 HSP (Us/cm)				





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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Power Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
RO Set Parameters Screen-2 Continue				
CT-201 Prolong Delay Timer (Secs)				
CT-202 HHSP (Us/cm)				
CT-202 HSP (Us/cm)				
CT-202 Prolong Delay Timer (Secs)				
PT-201 HSP (m3/Hr)				
PT-202 HSP (m3/Hr)				
CT-203 HHSP (Us/cm)				
CT-203 HSP (Us/cm)				
CT-203 Prolong Delay Timer (Secs)				
FT-202 CSP (m3/Hr)				
FT-202 LSP (m3/Hr)				
FT-203 CSP (m3/Hr)				
FT-203 LSP (m3/Hr)				
PH-202 HSP (DEG.C)				
PH-202 LSP (DEG.C)				
RO Set Parameters Screen-3				
TT-203 Heat SP (DEG.C)				
TT-203 Cool SP (DEG.C)				
TT-201 HSP (DEG.C)				
TT-201 CSP (DEG.C)				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Power Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
RO Set Parameters Screen-3 Continue				
TT-201 LSP (DEG.C)				
Sanitization Hold Timer (Min)				
Commutative Timer (Min)				
AV-205 Drain Timer (Secs)				
TT-202 CSP (DEG.C)				
TT-202 HSP (DEG.C)				
PT-201 HSP (m3/Hr)				
PT-202 HSP (m3/Hr)				
Post UF Parameters				
UF-201 Start-up-sequence Flushing Cycle (Secs)				
UF-201 Service Cycle (Mins)				
UF-201 Fast Flush (Secs)				
UF-201 Prolong Delay Time (Min)				
UF-201 Idle Time (Min)				
TT-203 Heat SP (DEG.C)				
TT-203 Cool SP (DEG.C)				
TT-204 HSP (DEG.C)				
TT-204 CSP (DEG.C)				
TT-204 LSP (DEG.C)				
TT-204 CSP (DEG.C)				



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QUALITY ASSURANCE DEPARTMENT

## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Power Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Post UF Parameters Continue				
TT-204 HSP (DEG.C)				
Sanitization Hold Timer (Min)				
Cumm Hold Timer (Min)				
RO Mimic Screen-1				
DP-203 Set%				
DP-202 Set%				
RO Mimic Screen-2				
ROHP-201 Set HZ				
PIDF-201 Set%				
RO Mimic Screen-3				
ROHP-202 Set HZ				
PIDF-202 Set%				
Post UF Parameters				
UFFP-201 Set HZ				

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 GENERATION SYSTEM

### 14.10 Verification of Communication Failure Condition

Objective : To verify the communication failure condition.

Tools : Not Applicable

Required

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		
Manufacturing Parameters				
PH-201 FS (PH)				
ORP-201 FS (mV)				
ORP-201 ZFS (mV)				
CT-201 FS (uS/cm)				
CT-202 FS (uS/cm)				
CT-203 FS (uS/cm)				
TT-201 FS (DEG.C)				
TT-202 FS (DEG.C)				
TT-203 FS (DEG.C)				



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Parameter Description	Communication Failure		Discrepancy ? (Y/N)	Done By Sign & Date	
	Parameter Value Before	Parameter Value After			
Manufacturing Parameters Continues					
TT-204 FS (DEG.C)					
FT-201 FS (m3/Hr)					
FT-202 FS (m3/Hr)					
FT-203 FS (m3/Hr)					
FT-204 FS (m3/Hr)					
FT-205 FS (m3/Hr)					
FT-206 FS (m3/Hr)					
PT-201 FS (bar)					
PT-202 FS (bar)					
PH-202 FS (PH)					
P Factor					
DP-202					
DP-203					
PIDV-201					
PIDV-202					
I Factor					
DP-202					
DP-203					
PIDV-201					
PIDV-202					
Manufacturing Parameters					
Temperature Hysteresis					
Flow Hysteresis					
RO Set Parameters Screen-1					
RO 1 Concentrate Flushing Time (Secs)					



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Parameter Description	Communication Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
RO Set Parameters Screen-1 Continue				
RO 1 Permeate Reject Time (Secs)				
RO 2 Concentrate Flushing Time (Secs)				
RO 2 Permeate Reject Time (Secs)				
EDI-201 OFF Delay Time (Secs)				
RO Flushing Delay Time (Secs)				
RO Idle Time (Min)				
ORP-201 HHSP (mV)				
ORP-201 CSP (mV)				
ORP-201 HSP (mV)				
ORP 201 Prolong Delay Timer (Secs)				
PH-201 HHSP (PH)				
PH-201 HSP (PH)				
PH-201 CSP (PH)				
PH-201 LSP (PH)				
PH-201 LLSP (PH)				
PH-201 Prolong Delay Timer (Secs)				
PH-201 Prolong Delay Timer (Secs)				
RO Set Parameters Screen-2				
CT-201 HHSP (Us/cm)				
CT-201 HSP (Us/cm)				



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QUALITY ASSURANCE DEPARTMENT

## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Communication Failure		Discrepancy ? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
RO Set Parameters Screen-2 Continue				
CT-201 Prolong Delay Timer (Secs)				
CT-202 HHSP (Us/cm)				
CT-202 HSP (Us/cm)				
CT-202 Prolong Delay Timer (Secs)				
PT-201 HSP (m3/Hr)				
PT-202 HSP (m3/Hr)				
CT-203 HHSP (Us/cm)				
CT-203 HSP (Us/cm)				
CT-203 Prolong Delay Timer (Secs)				
FT-202 CSP (m3/Hr)				
FT-202 LSP (m3/Hr)				
FT-203 CSP (m3/Hr)				
FT-203 LSP (m3/Hr)				
PH-202 HSP (DEG.C)				
PH-202 LSP (DEG.C)				
RO Set Parameters Screen-3				
TT-203 Heat SP (DEG.C)				
TT-203 Cool SP (DEG.C)				
TT-201 HSP (DEG.C)				
TT-201 CSP (DEG.C)				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Communication Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
RO Set Parameters Screen-3 Continue				
TT-201 LSP (DEG.C)				
Sanitization Hold Timer (Min)				
Commutative Timer (Min)				
AV-205 Drain Timer (Secs)				
TT-202 CSP (DEG.C)				
TT-202 HSP (DEG.C)				
PT-201 HSP (m3/Hr)				
PT-202 HSP (m3/Hr)				
Post UF Parameters				
UF-201 Start-up-sequence Flushing Cycle (Secs)				
UF-201 Service Cycle (Mins)				
UF-201 Fast Flush (Secs)				
UF-201 Prolong Delay Time (Min)				
UF-201 Idle Time (Min)				
TT-203 Heat SP (DEG.C)				
TT-203 Cool SP (DEG.C)				
TT-204 HSP (DEG.C)				
TT-204 CSP (DEG.C)				
TT-204 LSP (DEG.C)				
TT-204 CSP (DEG.C)				





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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Parameter Description	Communication Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Post UF Parameters Continues				
TT-204 HSP (DEG.C)				
Sanitization Hold Timer (Min)				
Cumm Hold Timer (Min)				
RO Mimic Screen-1				
DP-203 Set%				
DP-202 Set%				
RO Mimic Screen-2				
ROHP-201 Set HZ				
PIDF-201 Set%				
RO Mimic Screen-3				
ROHP-202 Set HZ				
PIDF-202 Set%				
Post UF Parameters				
UFFP-201 Set HZ				

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 GENERATION SYSTEM

### 14.11 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
Manufacturing Parameters				
PH-201 FS (PH)	0.00 to 99.99			
ORP-201 FS (mV)	-32768 to 32767			
ORP-201 ZFS (mV)	-32768 to 32767			
CT-201 FS (uS/cm)	0.0 to 999.9			
CT-202 FS (uS/cm)	0.0 to 999.9			
CT-203 FS (uS/cm)	0.00 to 99.99			
TT-201 FS (DEG.C)	0.0 to 999.9			
TT-202 FS (DEG.C)	0.0 to 999.9			
TT-203 FS (DEG.C)	0.0 to 999.9			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

Refer Attachment No.8					
Parameter	Specified	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date	
TT-204 FS (DEG.C)	0.0 to 999.9				
FT-201 FS (m3/Hr)	0.00 to 99.99				
FT-202 FS (m3/Hr)	0.00 to 99.99				
FT-203 FS (m3/Hr)	0.00 to 99.99				
FT-204 FS (m3/Hr)	0.00 to 99.99				
FT-205 FS (m3/Hr)	0.00 to 99.99				
FT-206 FS (m3/Hr)	0.00 to 99.99				
PT-201 FS (bar)	0.00 to 99.99				
PT-202 FS (bar)	0.00 to 99.99				
PH-202 FS (PH)	0.00 to 99.99				
P Factor					
DP-202	-999 to 999				
DP-203	-999 to 999				
PIDV-201	-999 to 999				
PIDV-202	-999 to 999				
I Factor					
DP-202	-999 to 999				
DP-203	-999 to 999				
PIDV-201	-999 to 999				
PIDV-202	-999 to 999				
Manufacturing Parameters					
Temperature Hysteresis	0.0 to 999.9				
Flow Hysteresis	-99.9 to 99.9				
RO Set Parameters Screen-1					



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

### Refer Attachment No.8

Parameter	Specified	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date	
RO 1 Concentrate Flushing Time (Secs)	0 to 999				
RO 1 Permeate Reject Time (Secs)	0 to 999				
RO 2 Concentrate Flushing Time (Secs)	0 to 999				
RO 2 Permeate Reject Time (Secs)	0 to 999				
EDI-201 OFF Delay Time (Secs)	0 to 999				
RO Flushing Delay Time (Secs)	0 to 999				
RO Idle Time (Min)	0 to 999				
ORP-201 HHSP (mV)	0 to 1500				
ORP-201 CSP (mV)	-32768 to 32767				
ORP-201 HSP (mV)	0 to 300				
ORP 201 Prolong Delay Timer (Secs)	0 to 300				
PH-201 HHSP (PH)	9.00 to 14.00				
PH-201 HSP (PH)	7.00 to 9.00				
PH-201 CSP (PH)	-99.99 to 99.99				
PH-201 LSP (PH)	6.00 to 8.00				
PH-201 LLSP (PH)	0.00 to 7.00				
PH-201 Prolong Delay Timer (Secs)	0 to 999				
PH-201 Prolong Delay Timer (Secs)	0 to 999				
RO Set Parameters Screen-2					
CT-201 HHSP (Us/cm)	-999.9 to 999.9				
CT-201 HSP (Us/cm)	-999.9 to 999.9				
CT-201 Prolong Delay Timer (Secs)	0 to 999				
CT-202 HHSP (Us/cm)	18.0 to 100.0				



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

### Refer Attachment No.8

Parameter	Specified	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
CT-202 HSP (Us/cm)	0.0 to 20.0			
CT-202 Prolong Delay Timer (Secs)	0 to 999			
PT-201 HSP (m3/Hr)	-99.99 to 99.99			
PT-202 HSP (m3/Hr)	-99.99 to 99.99			
CT-203 HHSP (Us/cm)	-99.99 to 99.99			
CT-203 HSP (Us/cm)	-99.99 to 99.99			
CT-203 Prolong Delay Timer (Secs)	0 to 999			
FT-202 CSP (m3/Hr)	-99.99 to 99.99			
FT-202 LSP (m3/Hr)	-99.99 to 99.99			
FT-203 CSP (m3/Hr)	-99.99 to 99.99			
FT-203 LSP (m3/Hr)	-99.99 to 99.99			
PH-202 HSP (DEG.C)	0.00 to 99.99			
PH-202 LSP (DEG.C)	0.00 to 99.99			
RO Set Parameters Screen-3				
TT-203 Heat SP (DEG.C)	-999.9 to 999.9			
TT-203 Cool SP (DEG.C)	-999.9 to 999.9			
TT-201 HSP (DEG.C)	-999.9 to 999.9			
TT-201 CSP (DEG.C)	-999.9 to 999.9			
TT-201 LSP (DEG.C)	-999.9 to 999.9			
Sanitization Hold Timer (Min)	1 to 120			
Commulative Timer (Min)	60 to 999			
AV-205 Drain Timer (Secs)	0 to 999			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

### Refer Attachment No.8

Parameter	Specified	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
TT-202 CSP (DEG.C)	0.0 to 999.9			
TT-202 HSP (DEG.C)	0.0 to 999.9			
PT-201 HSP (m3/Hr)	-99.99 to 99.99			
PT-202 HSP (m3/Hr)	-99.99 to 99.99			
Post UF Parameters				
UF-201 Start-up-sequence Flushing Cycle (Secs)	0 to 999			
UF-201 Service Cycle (Mins)	0 to 999			
UF-201 Fast Flush (Secs)	0 to 999			
UF-201 Prolong Delay Time (Min)	0 to 999			
UF-201 Idle Time (Min)	0 to 999			
TT-203 Heat SP (DEG.C)	0.0 to 99.9			
TT-203 Cool SP (DEG.C)	0.0 to 90.0			
TT-204 HSP (DEG.C)	0.0 to 99.9			
TT-204 CSP (DEG.C)	0.0 to 99.9			
TT-204 LSP (DEG.C)	-999.9 to 999.9			
TT-204 CSP (DEG.C)	0.0 to 999.9			
TT-204 HSP (DEG.C)	0.0 to 999.9			
Sanitization Hold Timer (Min)	1 to 120			
Cumm Hold Timer (Min)	60 to 999			
RO Mimic Screen-1				



**PHARMA DEVILS**

QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

**Refer Attachment No.8**

<b>Parameter</b>	<b>Specified</b>	<b>Actual Result</b>	<b>Discrepancy? (Yes/No)</b>	<b>Done By Sign &amp; Date</b>
DP-203 Set%	000.0 to 999.9			
DP-202 Set%	000.0 to 999.9			
RO Mimic Screen-2				
ROHP-201 Set HZ	00.0 to 99.9			
PIDF-201 Set%	000.0 to 999.9			



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## OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM

### Refer Attachment No.8

Parameter	Specified	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
RO Mimic Screen-3				
ROHP-202 Set HZ	00.0 to 99.9			
PIDF-202 Set%	000.0 to 999.9			
Post UF Mimic Screen				
UFFP-201 Set HZ	00.0 to 99.9			

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 GENERATION SYSTEM**

**15. OPERATIONAL QUALIFICATION TEST STATUS:**

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

<b>Test Description</b>	<b>Status (Pass / Fail)</b>	<b>Discrepancy? (Yes/No)</b>
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.



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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
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**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION SYSTEM**

**18. ABBREVIATION:**

<b>Abbreviations</b>	<b>Description</b>
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 GENERATION SYSTEM**

**19. ATTACHMENT SUMMARY:**

Attachment No.	Description

**20. OPERATIONAL QUALIFICATION SUMMARY & CONCLUSION:**

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**Compiled by:** \_\_\_\_\_ **Date:** \_\_\_\_\_



**OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF PURIFIED WATER GENERATION 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		