



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR  
PURIFIED WATER PRE-TREATMENT SYSTEM**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
PURIFIED WATER  
PRE-TREATMENT SYSTEM**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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**PROTOCOL CONTENTS**

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**1.0 PROTOCOL PRE- APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

**AUTHORIZED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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**2.0 OBJECTIVE:**

- The objective of this protocol (OQ protocol) is to establish confidence that the Pre-treatment system is capable of operating as per design and operating specifications.
- To verify proper operation of controllers, indicators, recorders, alarms, and interlocks.
- To verify the SOP's for start-up, operation, shut down and sanitization of the Pretreatment and Pretreatment System.
- Operate the Pretreatment System as per standard operating procedure to check all the operational verification.

**3.0 SCOPE:**

This procedure will be followed after completion of Installation Qualification of Pretreatment System. This document will also be followed at the time of installation or removal of any part in the existing Pretreatment System.



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Approval of the Operational Qualification Protocol cum report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Post Approval of Qualification Protocol cum report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout operation Qualification.</li><li>• Monitoring of operation Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Post Approval of Qualification Protocol cum report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum report.</li><li>• Assist in the Preparation of the Protocol cum report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.</li><li>• GA Drawing</li><li>• Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.</li><li>• Details of utilities</li><li>• Identification of components for calibration</li><li>• Material of construction of all components</li><li>• Brief Process Description</li><li>• Safety Features and Alarms</li><li>• Post Approval of Qualification Protocol cum report after Execution</li></ul>



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**5.0 RE-QUALIFICATION:**

- Any major modification in the existing Pre-treatment System since purchase, which can affect the quality of the product.
- If there is change in the location of the Pretreatment System.

**6.0 DESIGN SCHEME:**

**PRETREATMENT**

- NaOCl Dosing System
- Raw Water Pumps (1 W + 1 SB)
- Multi Grade Filter
- Softeners (1W + 1SB)
- Soft Water Tank
- UF Feed cum Fast Flush Pump
- 150 Micron Cartridge Filter
- Ultra Filtration System
- Back Flush Pump
- UF Water Tank

**7.0 PRE-QUALIFICATION REQUIREMENT:**

**7.1 Verification of Documents & General Arrangement Drawing:**

To verify that Approved Drawings and supporting documents of **Purified Water Pre-treatment System** conform to the Design Qualification.

**7.1.1 Procedure:**

- Verify that Approved Drawings and supporting documents are available and conform to the DQ Protocol Cum Report.
- If any deviation from DQ is observed during IQ, the same has to be recorded giving reasons for Deviation and Approved. Deviation should be approved by Authorized Person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol.



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**7.1.2 Acceptance Criteria:**

- Drawing and documents should conform to Design Qualification Protocol cum Report. Any Deviations observed must be Recorded and Approved.
- The General arrangement should confer to the approved GA Drawing. Any deviations observed, must be recorded and approved.

Pre-Qualification Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
<b>Drawing:</b>			
• <b>As build Isometric Drawing</b>	Should be as per approved Drawing		
• <b>As build P &amp; ID Drawing</b>	Should be as per approved P & ID Drawing		
<b>Certificates:</b>			
• <b>MOC Certificates for Tubes &amp; Fittings</b>	Should be available		
• <b>Hydro Test Certificate</b>	Should be available		
• <b>Passivation Certificate</b>	Should be available		
• <b>Sanitization Certificate</b>	Should be available		
• <b>Slope Verification Report</b>	Should be available		
• <b>Manuals of major brought out items</b>	Should be available		
• <b>Orbital Welding Printouts</b>	Should be available		
<b>Physical verification:</b>			
• <b>Horizontal leveling of the equipment</b>	Should be available		
• <b>Positioning of the equipment Erection of Loop System.</b>	Aligned vertically straight with sufficient space for maintenance		
• <b>Any physical damage to the equipment, floor, or room walls.</b>	No scratches or damage should exist.		
• <b>Weldings</b>	Orbital Welded for All Interconnecting Piping &		



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Pre-Qualification Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
	Argon Welding for Non Contact Parts.		

**Checked By:**  
**(Engineering)**  
**Sign & Date** \_\_\_\_\_

**Verified By:**  
**(Quality Assurance)**  
**Sign Date** \_\_\_\_\_

**Inference:** \_\_\_\_\_  
\_\_\_\_\_  
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**Reviewed By:**  
**(Manager QA)**  
**Sign Date** \_\_\_\_\_





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**7.2 Procedure**

**7.2.1 Calibration Instruments:**

The validation team will test and record the calibration data for the instruments that are going to be used for the calibration of the various equipment in the purified water system. In cases where the calibration instruments are Calibrated/Certified by an external agency, a certificate for the calibration should be attached to the OQ report.

The following checklist should be completed during the operational qualification by the validation team and added to the report.

S.No.	Instrument Used	Calibration done date	Calibration due on	Checked By
1.	Pressure gauge			
2.	Capacitance type Level Transmitter			
3.	Temperature Transmitter			
4.	Conductivity analyzer on line			
5.	Flow Transmitter			

**Checked By:**  
**(Engineering)**  
Sign & Date \_\_\_\_\_

**Verified By:**  
**(Quality Assurance)**  
Sign & Date \_\_\_\_\_

**Inference:** \_\_\_\_\_  
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**(Manager QA)**  
Sign Date \_\_\_\_\_



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**7.3 EQUIPMENT SPECIFICATIONS:**

**7.3.1 CHECK LIST OF PURIFIED WATER PRE-TREATMENT SYSTEM:**

S.No.	DESCRIPTION OF PURIFIED WATER PRE-TREATMENT SYSTEM:	YES/NO
1.	User Requirement Specification should be approved.	
2.	Equipment design data sheet should be prepared as per User Requirement Specification.	
3.	Equipment size should be match with space provided in the building for installation.	
4.	The periphery clearance should be adequate for area cleaning and manual operation.	
5.	Vertical clearance should adequate for area cleaning and Maintenance of the equipment.	
6.	Flow meter, Conductivity meter switch should be displayed on panel.	
7.	All pressure gauges filter housing, interconnecting pipe should be made of SS 316L.	
8.	UV light burning hour & intensity should be display on digital meter.	
9.	All sampling point should be clear & identify.	
10.	Gasket should be food grade silicone EPDM.	
11.	The system should have provision for sampling valve for validation purpose	
12.	The system should be control through SCADA and there is for Operation & critical alarm and warning.	

**Checked By:**  
**(Engineering)**  
**Sign & Date** \_\_\_\_\_

**Verified By:**  
**(Quality Assurance)**  
**Sign& Date** \_\_\_\_\_

**Inference:**-----  
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**Reviewed By:**  
**(Manager QA)**  
**Sign& Date** \_\_\_\_\_



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**7.4 KEY FUNCTIONALITY**

**Purpose:**

The purpose of this procedure is to demonstrate that the control panel of Pretreatment System provides the proper key functionality as specified by the manufacturer.

**Procedure:**

- Check that all the keys on the panel are properly Labeled/Identified.
- Turn on the power from the electrical panel.
- Verify key functionality of each component on the panel against its specified functions.
- Observe and record the responses of the control panel.

**Testing:**

Key/switch Description	Specified Function	Verification (Yes/No)
Main switch On/Off	To On/Off control panel	
Emergency switch	To stop the plant in any mode.	
Hooter Accept Button	To accept the Hooter alarm.	

**Inference:**-----  
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**Reviewed By:**  
**(Manager QA)**  
**Sign& Date**\_\_\_\_\_



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**7.5 DISPLAY FUNCTIONALITY**

**Purpose:**

The purpose of this procedure is to demonstrate that the control panel of Pretreatment System provides the proper display functionality as specified by the manufacturer.

**Procedure:**

- Check that all the displays on the panel are properly Labeled / Identified
- Turn on the power from the electrical panel
- Verify display functionality of each component on the panel against its specified functions
- Observe and record the responses of the control panel

**Testing:**

Display/Indication lamp Description	Specified Function	Verification (Yes / No)
Main supply	To indicate the condition / status of the three phases of power.	
IPC Alarm indication	To indicate the status of all operational activities in plant	

**Inference:**-----  
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**Sign& Date**\_\_\_\_\_



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**8.0 CRITICAL VARIABLES TO BE MET:**

PARAMETERS	DESCRIPTION
<b>1.FLOW RATES:</b>	
Test function	To check the Inlet/Outlet flow rates of system
Procedure	Operate the Pretreatment System as per given SOP. Check the flow rates at all input & output Rota meters of the system
Acceptance criteria	Required flow rates: <ul style="list-style-type: none"><li>• MGF-101 Feed: 7.5 m<sup>3</sup>/hr</li><li>• SF-101 Feed: 7.5 m<sup>3</sup>/hr</li></ul>
Remark:	
<b>2. NO FLOW IN RAW WATER FEED LINE (FS-101):</b>	
Test function	No flow at FS-101 in Raw Water Feed Line
Procedure	Stop the raw water flow and record the response.
Acceptance criteria	DP-101 should trip with indication on the panel.
Remark:	
<b>3. LOW LEVEL IN DOSING WATER TANK:</b>	
Test function	Low level in Dosing Tank
Procedure	Drain the water in the dosing Tank such that the level falls down to low level or set the low level value as per the actual level in the Tank & record the result.
Acceptance criteria	DP-101 will trip and AV-101 will close with indication on the panel.
Remark:	
<b>4. HIGH HIGH LEVEL IN RAW WATER TANK:</b>	
Test function	High High Level in Raw Water Tank
Procedure	Fill water in the Raw water Tank such that the level rises to High high level or set the high high level value as per the actual level in the Tank & record the result.
Acceptance criteria	DP-101 will trip and AV-101 will close.
Remark:	
<b>5. HIGH LEVEL IN RAW WATER TANK:</b>	
Test function	High level in Raw Water Tank
Procedure	Drain the water in the raw water Tank such that the level falls down to High level or set the High level value as per the actual level in the Tank & record the result.



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<b>PARAMETERS</b>	<b>DESCRIPTION</b>
<b>Acceptance criteria</b>	DP-101 will start and AV-101 will open
<b>Remark:</b>	
<b>6. LOW LEVEL IN RAW WATER TANK:</b>	
<b>Test function</b>	Low level in Raw Water Tank
<b>Procedure</b>	Drain the water in the Raw Water Tank such that the level falls down to low level or set the low level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	Should give alarm and indication on panel. RWP-101/102 will start
<b>Remark:</b>	
<b>7. LOW LOW LEVEL IN RAW WATER TANK:</b>	
<b>Test function</b>	Low Low level in Raw water Tank
<b>Procedure</b>	Drain the water in the raw water Tank such that the low low falls down to low Low level or set the low low level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	RWP-101/102 will trip.
<b>Remark:</b>	
<b>8. TOTALIZED FLOW AT OUTLET OF (SF-101/102):</b>	
<b>Test function</b>	Totalized flow at outlet of (SF-101/102)
<b>Procedure</b>	Set a value greater than the set point value of the OBR.
<b>Acceptance criteria</b>	System will go under regeneration automatically with alarm & indication on the panel.
<b>Remark:</b>	
<b>9. HIGH HIGH LEVEL IN SOFT WATER TANK:</b>	
<b>Test function</b>	High High level in Soft water Tank
<b>Procedure</b>	Do not consume water in the soft water Tank such that the level rises up to High High level or set the high High level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	RWP-101/102 will trip.
<b>Remark:</b>	
<b>10.HIGH LEVEL IN SOFT WATER TANK:</b>	
<b>Test function</b>	High level in Soft water Tank
<b>Procedure</b>	Drain the water in the soft water Tank such that the level falls down to



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PARAMETERS	DESCRIPTION
	High level or set the high level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	RWP-101/102 will start.
<b>Remark:</b>	
<b>11. LOW LEVEL IN SOFT WATER TANK:</b>	
<b>Test function</b>	Low level in Soft water Tank
<b>Procedure</b>	Drain the water in the Soft water Tank such that the level falls down to Low level or set the low level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	UFFP-101 will start.
<b>Remark:</b>	
<b>12. LOW LOW LEVEL IN SOFT WATER TANK:</b>	
<b>Test function</b>	Medium level in Soft water Tank
<b>Procedure</b>	Drain the water in the soft water Tank such that the level Falls Down to Low low level or set the medium level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	UFFP-101 will start.
<b>Remark:</b>	
<b>13. PRESSURE SWITCH (PS-101):</b>	
<b>Test function</b>	High Pressure at PS-101 than the pre-set value.
<b>Procedure</b>	Reset the Pressure Switch value in the operating condition below the operating feed pressure of the system. Perform this challenged test of Pressure switch. After an operation record the response.
<b>Acceptance criteria</b>	RWP-101/102 should trip with alarm & indication on the panel.
<b>Remark:</b>	
<b>14. PRESSURE SWITCH (PS-102):</b>	
<b>Test function</b>	High Pressure at PS-102 than the pre-set value
<b>Procedure</b>	Reset the Pressure Switch value in the operating condition below the operating feed pressure of the system. Perform this challenged test of Pressure switch. After an operation record the response.
<b>Acceptance criteria</b>	UF system should trip with alarm & indication on the panel.
<b>Remark:</b>	
<b>15. HIGH HIGH LEVEL IN UF WATER TANK:</b>	



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PARAMETERS	DESCRIPTION
<b>Test function</b>	High High level in UF water Tank
<b>Procedure</b>	Do not consume water in the UF water Tank such that the level rises up to High High level or set the High High level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	UFFP-101 will trip.
<b>Remark:</b>	
<b>16.HIGH LEVEL IN UF WATER TANK:</b>	
<b>Test function</b>	High level in UF water Tank
<b>Procedure</b>	Drain the water in the UF water Tank such that the level falls down to High level or set the High level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	UFFP-101 will start.
<b>Remark:</b>	
<b>17. LOW LEVEL IN UF WATER TANK:</b>	
<b>Test function</b>	Low level in UF Water Tank
<b>Procedure</b>	Fill the water in the UF water Tank such that the level rises up to Low level or set the Low Low level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	BFP-101 & ROFP-101 will start.
<b>Remark:</b>	
<b>18. LOW LOW LEVEL IN UF WATER TANK:</b>	
<b>Test function</b>	Low Low level in UF water Tank
<b>Procedure</b>	Drain the water in the UF Water Tank such that the level falls down to low level or set the low level value as per the actual level in the Tank & record the result.
<b>Acceptance criteria</b>	BFP-101 & ROFP-101 will trip with alarm & indication on the panel.
<b>Remark:</b>	
<b>19. EMERGENCY STOP:</b>	
<b>Test function</b>	Emergency stop
<b>Procedure</b>	Press Emergency Stop on main control panel during normal operation. Note the alarm is generated and indication shown on panel when Emergency Stop is pressed. Release the Emergency stop button. Switch ON the control power and reset the system. After an operation record the response.
<b>Acceptance criteria</b>	Emergency stop button shall be locked upon pressed. Pretreatment





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PARAMETERS	DESCRIPTION
	System should stop operation immediately. Audiovisual Alarm with indication on panel shall generate.
<b>Remark:</b>	

**Checked By:**  
**(Engineering)**  
**Sign & Date** \_\_\_\_\_

**Verified By:**  
**(Quality Assurance)**  
**Sign Date** \_\_\_\_\_

**Inference:** \_\_\_\_\_  
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**Reviewed By:**  
**(Manager QA)**  
**Sign Date** \_\_\_\_\_







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**15.0 ABBREVIATIONS:**

316L	: 316 Low carbon
AI	: Analog Input
AO	: Analog Output
ASTM	: American Society of Testing and Materials
cfu	: Colony forming unit
cGMP	: Current Good Manufacturing Practice
CI	: Cast Iron
cm <sup>2</sup>	: Square-centimeter
DI	: Digital Input
DO	: Digital Output
EPDM	: Ethylene Propylene Di Methylene
GA	: General Arrangement
HMI	: Human Machine Interface
LPH	: Liter per Hour
MOC	: Material of Construction
MWC	: Meter Water Column
OD	: Outside Diameter
OQ	: Operational Qualification
P&ID	: Piping & Instrumentation diagram
PLC	: Programmable Logical Control
PO	: Purchase Order
ppb	: Parts per billion
ppm	: Parts per million
PTFE	: Poly Tetra Flouro Ethylene
Ra	: Roughness average
SS	: Stainless Steel
SWG	: Standard Wire Gauge
TIG	: Tungsten Inert Gas Welding
VFD	: Variable frequency drive



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**16.0 PROTOCOL POST- APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

**AUTHORIZED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			