



PHARMA DEVILS

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QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

**OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION
SYSTEM**

**OPERATIONAL QUALIFICATION
PROTOCOL
FOR
PURIFIED WATER GENERATION
SYSTEM**



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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Operational Qualification protocol of purified water generation system been reviewed and approved by the following persons:

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		PROJECTS / ENGINEERING		
REVIEWED BY		PRODUCTION		
APPROVED BY		QUALITY ASSURANCE		



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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of this protocol is to collect sufficient data pertaining to the purified water generation system and define the operational qualification verification procedure and acceptance criteria for the purified water generation system.

2.2 PURPOSE:

The purpose of this document is to establish documentary evidence to ensure that the purified water generation system is operated as full range specification and also to ensure that it is comply the design specification.

2.3 SCOPE:

This document is applicable to operational qualification of purified water generation system at services floor.

2.4 RESPONSIBILITY:

The following shall be responsible:

Quality Assurance officer/ Executive-Preparation of protocol & its execution and support

Execution team –for execution of protocol

Projects / Engineering Head – For execution support and review of protocol/report

Production Head – For execution support and review of protocol/report

Quality Assurance Head – For adequacy and final approval

2.5 EXECUTION TEAM:



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The satisfactory installation of the purified water generation system shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the purified water generation system is operated satisfactorily.

Execution team is responsible for the execution of operational qualification of purified water generation system, Execution team comprises of:

NAME	DEPARTMENT	DESIGNATION	SIGNATURE	DATE
	PROJECTS/ ENGINEERING			
	PRODUCTION			
	QUALITY ASSURANCE			

3.0 ACCEPTANCE CRITERIA:

- 3.1 The equipment should be operational as per its specified operating instructions
- 3.2 All SOPs for the equipment shall be verified and checked
- 3.3 The purified water generation system shall be operated by PLC.
- 3.4 Training shall be given to all the concerned personnel.
- 3.5 All the functionality of equipment & components to shall be verified.
- 3.6 All the safety features/interlocking system of the equipment shall be verified.
- 3.7 The validity of the calibration of tests instruments shall be checked and all the required calibration of the components of the equipment shall be performed.

4.0 REQUALIFICATION CRITERIA:

The purified water generation system shall be re qualified if

- ☞ There are any major changes in system components which affect the performance of the system.
- ☞ After major breakdown maintenance is carried out.
- ☞ After change in the location
- ☞ As per revalidation date and schedule

5.0 OPERATIONAL QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

Equipment Name : Purified water generation System



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Supplier/Manufacturer :

Capacity : 3300 LPH

Location :

Water is fed in Reverse Osmosis system with the help of RO Feed Pump at the rate of 6.0 m³/hr. with the help of RO feed Pump.

Sodium Meta bi sulphate (Na₂S₂O₅) is then dosed in the chlorinated water to neutralize the free chlorine (excess chlorine) present in the water.

Anti scalent Dosing System is then dosed in the soft water to avoid scale formation on the RO Membranes.

Auto pH Correction Dosing System is provided to adjust the feed pH of RO feed water as 7.0 - 8.2. Reverse Osmosis Pass-I System removes dissolved solids and decreases conductivity. ORP Analyzer is provided so as to check the absence/presence of chlorine in the feed water to the RO System. If free chlorine is sensed in the feed water it will give an indication on the panel & open the dumping valve and dump the high ORP water for 300 secs. & Even if the ORP value is not below the set point it will trip the system.

Water is then fed to the Reverse Osmosis Pass-I System by means of a High Pressure Vertical multistage Pump with SS 316 wettable parts of M/s. Grundfos, Denmark. The Reverse Osmosis System will generate 3600 liters/hr water with an overall recovery of 70 %. The generated water will have Conductivity < 150 µs/cm. The Reverse Osmosis membrane acts as positive barrier to remove dissolved solids, organic compounds & bacteria. The Reverse Osmosis System consists of thin film composite type Reverse Osmosis membrane of Dow. The material of construction of the RO membrane is Polyamide. The RO membrane is housed in the High Pressure SS 316L Wettable Parts Housing having TC end connection and hot water Sanitizable. Purity level of Water will be as per WHO & Drinking Water Standards at the outlet of Reverse Osmosis Pass – II.

Water is then fed to the Reverse Osmosis Pass-II System by means of a High Pressure Vertical multistage Pump with SS 316 wettable parts of M/s. Grundfos, Denmark. The Reverse Osmosis System will generate 3900 liters/hr water with an overall recovery of 80%. The generated water will have Conductivity < 15-20 µs/cm. The semi-permeable

reverse osmosis membrane has molecular weight cut off less than 150 MWCO. The Reverse Osmosis membrane acts as positive barrier to remove dissolved solids, organic compounds & bacteria.

The Reverse Osmosis System consists of thin film composite type Reverse Osmosis membrane of Dow. The material of construction of the RO membrane is Polyamide. The RO membrane is housed in the High Pressure SS 316L Wettable Parts Housing having TC end connection and hot water Sanitizable. The Permeate water from RO System will be fed to the Electro Deionization Unit (EDI) having designed capacity of 3500 LPH. The EDI system has a recovery of 90%. The Permeate water from EDI is stored into UF feed tank of capacity 0.5 KL. The stored water is transferred by UFFP of capacity 7.0 m³/hr, part of water is re circulated into UF feed



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tank & remaining is fed to UF system. The water generated from the outlet of UF will be as per USP 34 Standards for Purified Water.

- ❖ RO Feed Pump
- ❖ SMBS Dosing System
- ❖ ADS Dosing System
- ❖ Auto pH Dosing System
- ❖ Cartridge Filter
- ❖ ORP Analyzer along with auto dumping valve
- ❖ RO High Pressure Pumps for first pass
- ❖ Reverse Osmosis Membranes along with High Pressure Housings for first pass
- ❖ Conductivity Analyzer with auto dumping valve for first pass
- ❖ RO High Pressure Pumps for second pass
- ❖ Reverse Osmosis Membranes along with High Pressure Housings for second pass
- ❖ Conductivity Analyzer with auto dumping valve for second pass
- ❖ EDI Unit
- ❖ Conductivity Analyzer with auto dumping valve for EDI unit
- ❖ **ULTRA FILTRAION SYSTEM**
- ❖ UF Feed Tank
- ❖ UF Feed Pump
- ❖ UF Membranes along with the Housing

5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.

5.3 TEST INSTRUMENT DETAILS:

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation.

S.No.	Name of Instrument	Inst. ID. No.	Calibration Valid up to	Checked
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5.4 VERIFICATION OF FUNCTIONAL & KEY FUNCTIONAL PARAMETERS:



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5.4.1 Initial set parameters shall be verified before starting the operational qualification:

S.No.	Parameters	Set Parameters	Method of Verification	Observation	Verified by Sign & Date
1.	ORP set value	400 mv	Set ORP valve shall be verified by visual observation in HMI		
2.	EDI out let conductivity	1.25 us/cm	Set EDI outlet conductivity shall be verified by visual observation in HMI		
3.	UF normal mode time	15000 secs.	Set UF normal mode time shall be verified by visual observation in HMI		
4.	UF fast flushing time	600 secs.	Set UF fast flushing time shall be verified by visual observation in HMI		
5.	Conductivity of pass-I	150 us/cm	Set conductivity of pass-I shall be verified by visual observation in HMI		
6.	Conductivity of pass-II	15 us/cm	Set conductivity of pass-II shall be verified by visual observation in HMI		
7.	High - High Level of EDI Storage Tank	500 Ltrs	Set High - High Level shall be verified by visual observation in HMI		
8.	High Level of EDI Storage Tank	350 Ltrs	Set High Level shall be verified by visual observation in HMI		



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S.No.	Parameters	Set Parameters	Method of Verification	Observation	Verified by Sign & Date
9.	Low Level of EDI Storage Tank	200 Ltrs	Set Low Level shall be verified by visual observation in HMI		
10.	Low -Low level of EDI Storage Tank	50 Ltrs	Set Low -Low level shall be verified by visual observation in HMI		
11.	Sanitization level	350 Ltrs	Set Sanitization level shall be verified by visual observation in HMI		
12.	Time for Sanitization	60 minutes	Set Time for Sanitization shall be verified by visual observation in HMI		
13.	Temperature control HYST	2 °C	Set temperature shall be verified by visual observation in HMI		

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5.4.2 VERIFICATION OF KEY FUNCTIONALITY:

The key functionality of purified water generation system shall be verified as per following.

Name of components	Procedure	Acceptance criteria	Observation	Verified by sign & date
Main switch ON/OFF	<ul style="list-style-type: none">☞ Switch ON the main switch and observe.☞ Switch OFF the main switch and observe.	Power supply to the control panel should start. Power supply to the control panel should stop.		
RO Auto-Manual selector switch	Switch the selector switch at auto & manual position by manually and check	Two way switch provided for change over from RO plant Auto to manual operation or vice versa		
Post UF Auto-Manual selector switch	Switch the selector switch at auto & manual position by manually and check	Two way switch provided for change over from post UF plant Auto to manual operation or vice versa		
HMI	Touch the HMI by finger and check the different level of operation	Touch screen provided for different mode for generation operation plant. (Auto & Manual)		
Green Push start button for RO feed pump (ROFP-101)	Push the start button by manually and check.	RO feed pump should start in manual mode and green light should glow.		
Red Push stop button for RO feed pump (ROFP-101)	Push the stop button by manually and check.	RO feed pump should stop in manual mode and red light should glow.		



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Name of components	Procedure	Acceptance criteria	Observation	Verified by sign & date
Green Push start button for RO high pressure pump (ROHP-101)	Push the start button by manually and check.	RO high pressure pump should start in manual mode and green light should glow.		
Red Push stop button for RO high pressure pump (ROHP-101)	Push the stop button by manually and check.	RO high pressure pump should stop in manual mode and red light should glow.		
Green Push start button for RO high pressure pump (ROHP-102)	Push the start button by manually and check.	RO high pressure pump should start in manual mode and green light should glow.		
Red Push stop button for RO high pressure pump (ROHP-102)	Push the stop button by manually and check.	RO high pressure pump should stop in manual mode and red light should glow.		
Green Push start button for EDI.	Push the start button by manually and check.	EDI system should start in manual mode and green light should glow.		
Red Push stop button for EDI.	Push the stop button by manually and check.	EDI should stop in manual mode and red light should glow.		
Green Push start button UFFP-101	Push the start button by manually and check.	UF feed pump should start in manual mode and green light should		



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Name of components	Procedure	Acceptance criteria	Observation	Verified by sign & date
		glow.		
Red Push stop button for UFFP-101	Push the stop button by manually and check.	UF feed pump should stop in manual mode and red light should glow.		
Hooter reset button	Press the reset button manually when acknowledge the alarm	To reset the hooter alarm		
Emergency push button	Push the emergency push button during running of system	System should stop immediately.		

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5.4.3 VERIFICATION OF OPERATIONAL SEQUENCE:

Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
GENERATION PLANT AUTO MODE OPERATION				
Power supply	Switch ON the main supply from the selector switch.	Power supply to the control panel should start.		
Main switch ON	Turn the main switch to ON position and observe	HMI should start booting and welcome screen should appear.		
Plant selection screen	Touch the welcome screen and observe	Plant selection screen should appear with following plants Generation plant Post UF Distribution		
Generation plant	Select the generation plant from the HMI.	Generation plant should select and screen with select menu of auto and manual mode should appear.		
Auto mode	Select the auto mode and observe.	Password screen for auto mode operation should appear.		
Login	Enter the correct password and press the next key	Auto mode screen with following		



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
	and observe	parameters should appear Select mode Auto mode ON/OFF key Start key Stop key Process parameter key Set parameter key Sanitization key Main. Key PID Key Auto flushing key Alarm key Overview key		
Auto mode ON/OFF key	Press the auto mode ON/OFF key and observe.	Auto mode should ON and OFF by pressing auto ON/OFF key.		
Start key	Press the start key and observe	Auto mode should start		
Stop key	Press the stop key and observe	Auto mode should stop		



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
Set parameters key	Press the set parameters key and observe.	Screen with supervisory login should appear.		
Login	Enter the correct supervisory password and press next key	Set parameter screen 1 should appear.		
ORP value	Select the ORP value option and set the ORP value in the range -1000 to 1000	ORP value should set in the given range.		
RO1 outlet cond.	Select the RO1 outlet cond. Option and enter the value in the range 0-200 μ s/m	RO1 outlet cond. Value should et in the given range.		
RO2 outlet cond.	Select the RO2 outlet cond. Option and enter the value in the range 0-50 μ s/m	RO2 outlet cond. Value should et in the given range.		
EDI outlet cond.	Select the EDI outlet cond. Option and enter the value in the range 0-20 μ s/m	EDI outlet cond. value should et in the given range.		
Flushing OFF time	Select the flushing OFF time option and set the value in the range 0-32000 sec.	Flushing OFF time should set in the given range.		
Flushing ON time	Select the flushing ON time option and set the value in the range 0-32000 sec.	Flushing ON time should set in the given range.		
RO1 reject flow set	Select the RO1 reject flow set option and enter the value in the range 0-32000 LPH	RO1 reject flow set in the given range		



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RO2 reject flow set	Select the RO2 reject flow set option and enter the value in the range 0-32000 LPH	RO2 reject flow set in the given range		
Print interval	Select the print interval option and set the print interval in the range 0-32000sec.	Print interval should set in the given range.		
UF permeate Low flow	Select the UF permeate low flow and enter the value in the range 0-32000 LPH	UF permeate Low flow should set in the given range.		
UF normal mode time	Select the UF normal mode time and enter the value in the range 0-32000 sec.	UF normal mode time should set in the given range.		
UF fast flush mode time	Select the UF fast flush mode time and enter the value in the range 0-32000 sec.	UF fast flush mode time should set in the given range.		
>>> next key	Press the next key and observe	Set parameter Screen 2 “ RO sanitization parameter should appear”		
Sanitization time	Select the sanitization time option and enter the value in the range 1-999 min.	Sanitization time should set in the given range		
SAN. Start Temp.	Select the sanitization start temperature option and enter the value in the range 0-85°C	SAN. Start Temp. value should set in the given range.		
Temp. control Hysteresis	Select the Temp. control Hysteresis option and enter the value in the range 0-20 °C	Temp. control Hysteresis value should set in the given range.		



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
PIDV1 sanitization O/P	Select the PID1 sanitization O/P option and set the value in the range 10-100%	PIDV1 sanitization O/P value should set in the given range.		
PIDV2 sanitization O/P	Select the PID2 sanitization O/P option and set the value in the range 10-100%	PIDV2 sanitization O/P value should set in the given range.		
Process Parameters	Select the process parameters option from the auto mode operation screen and observe	Process parameters screen1 and 2 should appear with parameters in display mode only.		
Auto mode flush	Select the auto mode flush option from the auto mode operation screen and observe	Auto mode flushing screen should appear		
Select mode Flushing mode ON/OFF Key	Turned the flushing mode to ON position and start the auto flushing by pressing start button.	Auto flushing should start.		
Stop button	Press the stop button and observe	Auto flushing should stop.		
Sanitization mode screen	Select the sanitization mode screen from the auto mode operation screen and observe	Sanitization mode screen should appear.		
Select mode sanitization mode ON/OFF	Turned the sanitization mode to ON position and start the sanitization by pressing start button.	Sanitization should start.		



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
Key				
Stop button	Press the stop button and observe	Sanitization should stop.		
Overview option	Select the overview option from the auto mode operation screen and observe the	Screen-1,2,3 with P & ID parameters should appear with		
Auto mode operation	After setting the all the parameters start the auto mode operation and observe.	RO feed pump should be started (ROFP-01) RO high pressure pump should be started (ROHP-01) The conductivity of RO pass –I should display in CIC-01 RO high pressure pump should be started (ROHP-02) The conductivity of RO pass –II should display in CIC-02 EDI system should be ON and EDI voltmeter should show the readings.		
GENERATION PLANT MANUAL MODE OPERATION				
Generation plant	Select the Generation plant from the HMI.	Generation plant should select and screen with select menu of auto and manual mode		



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
		should appear.		
Manual mode	Select the manual mode and observe.	Password screen for manual mode operation should appear.		
Login	Enter the correct password and press the next key and observe	Manual mode screen with following parameters should appear Mode select manual mode ON/off key SMBS ON/OFF ADS ON/OFF pHC ON/OFF ROFP ON/OFF ROHP1 ON/OFF ROHP2 ON/OFF EDI ON/OFF CIPFP ON/OFF CIP HTR ON/OFF AV101 ON/OFF AV102 ON/OFF		



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		AV103 ON/OFF AV104 ON/OFF AV105 ON/OFF AV106 ON/OFF FDV-101 ON/OFF		
Mode select manual mode ON/off key	Select the manual mode ON/OFF key and observe	Manual mode should ON/OFF		
SMBS ON/OFF key	Touch the SMBS to ON/OFF position and observe	SMBS dosing pump should start and stop by touching off key		
ADS ON/OFF key	Touch the ADS to ON/OFF position and observe	ADS dosing pump should start and stop by touching off key		
pHC ON/OFF key	Touch the pHC to ON/OFF position and observe	pH dosing pump should start and stop by touching off key		
ROFP ON/OFF key	Touch ROFP to ON/OFF position and observe	RO feed pump should start and stop by touching off key		
ROHP1	Touch ROHP1 to ON/OFF position and observe	RO High pressure pump1 should start and		



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ON/OFF key		stop by touching off key		
ROHP2 ON/OFF key	Touch ROHP2 to ON/OFF position and observe	RO High pressure pump 2 should start and stop by touching off key		
AV-101 ON/OFF KEY	Touch AV-101 to ON/OFF position and observe	Actuated valve AV-101 should open and close		
AV-102 ON/OFF KEY	Touch AV-102 to ON/OFF position and observe	Actuated valve AV-102 should open and close		
AV-103 ON/OFF KEY	Touch AV-103 to ON/OFF position and observe	Actuated valve AV-103 should open and close		
AV-104 ON/OFF KEY	Touch AV-104 to ON/OFF position and observe	Actuated valve AV-104 should open and close		
AV-105 ON/OFF KEY	Touch AV-105 to ON/OFF position and observe	Actuated valve AV-105 should open and close		
AV-106 ON/OFF KEY	Touch AV-106 to ON/OFF position and observe	Actuated valve AV-106 should open and close		
FDV-101 ON/OFF KEY	Touch FDV-101 to ON/OFF position and observe	Flow Diverter valve FDV-101 should open and close		

POST UF PLANT



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
Post UF plant	Select the post UF plant from the plant selection screen and observe	Operation mode screen auto/manual screen should appear.		
Auto mode	Select the auto mode and observe.	Password screen for auto mode operation should appear.		
Login	Enter the correct password and press the next key and observe	Auto mode screen with following parameters should appear Select mode Auto mode ON/OFF key Start key Stop key Process parameter key Set parameter key Sanitization key Main. Key Alarm key Overview key		
Auto mode ON/OFF key	Press the auto mode ON/OFF key and observe.	Auto mode should ON and OFF by pressing auto ON/OFF key.		



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Start key	Press the start key and observe	Auto mode should start		
Stop key	Press the stop key and observe	Auto mode should stop		
Set parameters key	Press the set parameters key and observe.	Screen with supervisory login should appear.		
Login	Enter the correct supervisory password and press next key	Set parameter screen 3 should appear.		
UF tank HH level	Select the UF tank HH level option and enter the value in the range 0-9999 Ltr.	UF tank HH level value should enter in the given range.		
UF tank H level	Select UF tank H level option	UF tank H level value should display.		
UF tank L level	Select UF tank L level option	UF tank L level value should display.		
UF tank LL level	Select the UF tank LL level option and enter the value in the range 0-9999 Ltr.	UF tank LL level value should enter in the given range.		
Sanitization time	Select the sanitization time and enter the value in the range 1-999 min.	Sanitization time should set in the given range.		
Sanitization start temperature	Select the PWS sanitization start temperature and set the value in the range 0-90°C	Sanitization start temperature value should set in the given range.		
Temp. control	Select the Temp. control Hysteresis and set the	Temp. control Hysteresis value should set		



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Hysteresis	value in the range 0-20°C	in the given range.		
EVF control temperature	Select the EVF control temperature and set the value in the range 0-85°C	EVF control temperature value should set in the given range.		
EVF temperature HYSTR.	Select the EVF temperature HYSTR. and set the value in the range 0-20°C	EVF temperature HYSTR. value should set in the given range.		
UF tank sanitization level	Select the UF tank sanitization level and enter the value in the range 0-9999 L	UF tank sanitization level value should set in the given range.		
MANUAL MODE OPERATION				
Manual mode	Select the manual mode and observe.	Password screen for manual mode operation should appear.		
Login	Enter the correct password and press the next key and observe	Manual mode screen with following parameters should appear Mode select manual mode ON/off key UFFP ON/OFF ADV-101 ON/OFF		



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PROTOCOL No.:

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
		AV-107 ON/OFF AV-108 ON/OFF ADV-102 ON/OFF EVF-101 ON/OFF		
UFFP ON/OFF key	Turned the UFFP pump to ON/OFF position and observe	UF feed pump should start and stop by pressing off key.		
ADV-101 ON/OFF	Turned the ADV-101 to ON/OFF position and observe	Actuated diaphragm valve should open and close by pressing off key.		
AV-107 ON/OFF	Turned the AV-107 to ON/OFF position and observe	Actuated valve should open and close by pressing off key.		
AV-108 ON/OFF	Turned the AV-108 to ON/OFF position and observe	Actuated valve should open and close by pressing off key.		
ADV-102	Turned the ADV-102 to ON/OFF position and	Actuated diaphragm valve should open and		



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ON/OFF	observe	close by pressing off key.		
EVF-101 ON/OFF	Turned the EVF-101 to ON/OFF position and observe	Vent filter should open and close by pressing off key.		
Manual Mode sanitization of RO membrane & EDI	Put the system in sanitization mode turn ON in manual mode. Close the pneumatic & diaphragm valve AV101to AV105 & AV06 simultaneously ball valve BV101&NV104 shall be closed and open the inlet/outlet valve of RO feed pump ,high pressure pump 1&2 and RO pass-I & II reject line valve . Open the ball valve of steam inlet to EDI storage tank. And start the RO system as per manual operation.	<ul style="list-style-type: none"> ☞ Water should be heated up to 83⁰C. ☞ After water reaches 83⁰C start the sanitization manually for 60 min. 		
Auto Mode sanitization of UF system	Put the system in sanitization mode turn ON auto mode. Welcome screen appear on the screen Post UF ► auto ► login ► sanitization mode ► start the system, when temperature reach the 83 ^o c display in HMI sanitation time shall be stared	<ul style="list-style-type: none"> ☞ Water should be heated up to 83⁰C. ☞ After water reaches 83⁰C Sanitization Timer starts for 60 min. 		



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Test Parameters	Procedure	Acceptance Criteria	Observation	Verified by Sign & Date
	automatically.			

Inference: -----

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5.5 VERIFICATION OF PROVIDED INTERLOCKING / SAFETY FEATURE:

All interlocking/safety feature provided in system shall be verified as per following procedure:

Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
Flow rate verification	Operate the Purified Water Storage & generation System as per the standard operating procedure and check the input & output rota meters of the system	<ul style="list-style-type: none"> ☞ RO pass-I feed should be 8.5 m³/hr. ☞ RO pass-I permeated should be 4.9 m³/hr. ☞ RO pass-I reject should be 1.5 m³/hr. ☞ RO pass-II feed should be 6.9 m³/hr. ☞ RO pass-I permeated should be 3.9 m³/hr. ☞ RO pass-I reject should be 1.0 m³/hr. ☞ EDI dilute inlet 3.9 m³/hr. ☞ EDI concentration inlet 0.4 m³/hr. ☞ EDI outlet 3.5 m³/hr. ☞ UF feed 3.5 m³/hr. ☞ UF reject 0.2 m³/hr. 		



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Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
		☞ UF outlet 3.3 m ³ /hr.		
Low level switch in SMBS tank	Pull the low level switch from the SMBS dosing tank and check.	Alarm should be generated and system shall trip.		
Low level switch in ADS tank	Pull the low level switch from the ADS dosing tank and check.	Alarm should be generated and system shall trip.		
Low level switch in pH correction tank	Pull the low level switch from the pH correction tank and check.	Alarm should be generated and system shall trip.		
ORP trans meter	Stop the SMBS dosing and allow the high chlorinated water pass through ORP sensor and check the response.	If ORP value more than the set ORP value chlorinated water should be dumped. If ORP value continuous more than 5 minute high alarm generated & system shall trip.		
Low pressure switch at inlet of RO high pressure pump-I	Set the low pressure switch value in operating condition above the operating feed pressure of RO system.	RO high pressure pump-I shall trip, if it will trip 4 times in a minute then entire system shall trip with generating the alarm.		
High pressure switch at	Set the high pressure switch value in	Purified water generation system shall		



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Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
outlet of RO high pressure pump-I	operating condition below the operating feed pressure of RO system.	trip with generating the alarm.		
High conductivity at RO permeate (Pass-I)	Set the conductivity below the actual set conductivity value	Dumping valve should open immediately and dumped the permeated water, if consistence 5 minutes dumping then system shall trip with alarm generated in system. After getting conductivity original set valve after 30 seconds consistence low value dumping valve automatically close and system shall be restarted.		
Low pressure switch at inlet of RO high pressure pump-II	Set the low pressure switch value in operating condition above the operating feed pressure of RO system.	RO high pressure pump-I shall trip, if it will trip 4 times in a minute then entire system shall trip with generating the alarm.		
High pressure switch at outlet of RO high pressure pump-II	Set the high pressure switch value in operating condition below the operating feed pressure of RO system.	Purified water generation system shall trip with generating the alarm.		
High conductivity at RO	Set the conductivity below the actual set	Dumping valve should open		



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Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
permeate (Pass-II)	conductivity value	immediately and dumped the permeated water, if consistence 5 minutes dumping then system shall trip with alarm generated in system. After getting conductivity original set valve after 30 seconds consistence low value dumping valve automatically close and system shall be restarted.		
Low pressure switch at EDI inlet	Set the low pressure switch value in operating condition above the operating feed pressure of EDI system.	EDI system shall trip, if EDI system shall trip 4 times in a minutes entire system shall trip with generating alarm.		
High conductivity at EDI permeate	Set the conductivity below the actual set conductivity value	Dumping valve should open immediately and dumped the permeated water, if consistence 5 minutes dumping then system shall trip with alarm generated in system. After getting conductivity original set valve after 30 seconds consistence low value dumping valve automatically		



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Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
		close and system shall be restarted.		
High High level in UF feed tank	Fill the water without consuming from the UF feed tank up to high high level sensor and observe	As soon as the high high level is achieved in the UF feed tank, generation system should go in auto flushing mode with HH level alarm generated on HMI		
High level in UF feed tank	Drain the water from the UF feed tank such that the level in the UF feed tank falls down to High level or set the high level value as per the actual level in the tank.	As soon as the high level is achieved in the UF feed tank, generation system should start automatically in normal mode in normal sequence.		
Low-low level in UF feed tank	Drain the water from the UF feed tank such that the level in the UF feed tank falls down to Low -Low level.	As soon as the Low-Low level is achieved in the UF feed tank, UF feed pump shall stop immediately.		
Low level in UF feed tank	Fill the water in the UF feed tank such that the level in the UF feed tank reaches to Low level.	As soon as the Low level is achieved in the UF feed tank, UF feed pump will start immediately.		
Low temperature at inlet of Post UF system during	Operate Post UF system in Sanitization mode.	The Steam Valve AV-107 will Open.		



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Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
sanitization	Reset the low temperature limits higher than the actual temperature value of post UF system.			
High temperature at inlet of post UF system during sanitization	Operate Post UF system in Sanitization mode. Reset the temperature limits below than the actual temperature value of post UF system.	The Steam Valve AV-107 will close.		
Pressure switch at inlet of post UF system	Reset the pressure switch value in operating condition below the operating feed pressure of the post UF system	UF feed pump will trip with an alarm indication on the panel.		
Change over from Auto mode to PLC manual mode and vice versa	Start the system in auto mode the immediate turn on in manual mode or vice versa.	Generation system should trip completely during changeover the mode.		
PLC manual Mode	Select the manual mode provided in the PLC and press the keys on the touch screen to start/stop the dosing pumps, EDI & control valve.	All pumps dosing pump EDI, control valve should start & stop after manually pressing the keys provided on touch screen.		



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Interlock/safety feature description	Procedure	Acceptance criteria	Observation	Verified by sign& date
Emergency stop	Press Emergency Stop on main control panel during normal operation. Note the alarm is generated and message is displayed on MMI when Emergency Stop is pressed. Release the Emergency stop button. Switch ON the control power and reset the system.	E-stop button shall be locked upon pressed. Purified Water Generation should stop operation immediately. Audio visual Alarm shall generate.		

Inference: -----

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5.6 REVIEW OF CALIBRATION STATUS OF MEASURING DEVICES:

S.No.	Instrument Name	Instrument ID No.	Calibration Done on	Calibration Due on	Verified By Sign & Date

Inference:

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5.7 Verification of Standard Operating Procedure:

All identified standard operating procedure shall be verified during operational qualification of system.

S.No.	SOP Title	SOP No.	Status	Verified by Sign& Date

Inference:

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(Sign/Date)



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5.9 ABBREVIATIONS:

Following Abbreviations are used in the installation qualification protocol of purified water generation system

mm : Millimeter

m/sec : Meter/second

P & ID : Piping & instrumentation diagram

PW : Purified water

NMT : Not more than

NLT : Not less than

HMI : Human machine interface

μ S/cm : Micro Siemens per centimeter

PWG : Purified water generation

POQ : Protocol for operational qualification

ROQ : Report for operational qualification

ORP : Oxidation Reduction potential



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5.10 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of Deficiency: -----

Corrective Action(s) taken: -----

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Sign & Date**



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6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

The Operational Qualification final Summary & Conclusion shall be written in below given space.

6.1 Summary: -----

6.2 Conclusion : -----

Reviewed By

Sign & Date



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6.3 FINAL REPORT APPROVAL:

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol, (if applicable)

Signatures in the block below indicate that all items in this qualification report of Purified water Generation system have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PROJECTS / ENGINEERING		
		PRODUCTION		
		QUALITY ASSURANCE		