OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

PURIFIED WATER

GENERATION SYSTEM

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

PROTOCOL CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

2.0 OBJECTIVE:

Objective

- The objective of this protocol (OQ protocol) is to establish confidence that the Purified Water Generation 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 Purified Water Generation System.
- Operate the Purified Water Generation 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 Purified Water Generation System. This document will also be followed at the time of installation or removal of any part in the existing Purified Water Generation System.

Re-Qualification:

Operation Qualification to be re-qualified on:

- Any major modification in the existing Purified Water Generation System since purchase, which can affect the quality of the product.
- If there is change in the location of the Purified Water Generation System.

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of the Operational Qualification Protocol cum report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Qualification Protocol cum report after Execution. • Co-ordination with Production and Engineering to carryout operation Qualification. • Monitoring of operation Qualification Activity.
Production	• Review of the Protocol cum report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Qualification Protocol cum report after Execution.
Engineering	• Review of the Protocol cum report. • Assist in the Preparation of the Protocol cum report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. • GA Drawing • Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures. • Details of utilities • Identification of components for calibration • Material of construction of all components • Brief Process Description • Safety Features and Alarms • Post Approval of Qualification Protocol cum report after Execution

5.0 RE-QUALIFICATION:

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

6.0 DESIGN SCHEME:

PURIFIED WATER GENERATION SYSTEM

- RO Feed Pump
- SMBS Dosing System
- ADS Dosing System
- Auto pH Correction Dosing System
- 5 Micron Cartridge Filter
- ORP Analyzer along with auto dumping valve
- RO High Pressure Pump for Pass-1
- Reverse Osmosis Membranes along with High Pressure Housings for Pass-1
- Conductivity Analyzer with auto dumping valve for Pass-1
- RO High Pressure Pump for Pass-2
- Reverse Osmosis Membranes along with High Pressure Housings for Pass-2
- Conductivity Analyzer with auto dumping valve for Pass-2
- EDI Unit
- CIP Feed Tank
- CIP Feed Pump
- High Intensity Ultra Violet Unit

7.0 PRE-QUALIFICATION REQUIREMENT:

7.1 Verification of Documents & General Arrangement Drawing:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

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.

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
Drawing:			
• **As build Isometric Drawing**	Should be as per Approved Drawing		
• **As build P & ID Drawing**	Should be as per Approved P & ID Drawing		
Certificates:			
• **MOC Certificates for Tubes & Fittings**	Should be available		
• **Hydro Test Certificate**	Should be available		
• **Passivation Certificate**	Should be available		
• **Sanitization Certificate**	Should be available		
• **Slope Verification Report**	Should be available		
• **Manuals of major brought out items**	Should be available		
• **Orbital Welding Printouts**	Should be available		
Physical verification:			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

Pre-Qualification Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign & Date
• **Horizontal leveling of the equipment**	Should be available		
• **Positioning of the equipment Erection of Loop System.**	Aligned vertically straight with sufficient space for maintenance		
• **Any physical damage to the equipment, floor, or room walls.**	No scratches or damage should exist.		
• **Weldings**	Orbital Welded for All Interconnecting Piping & 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_____

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

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 Generation 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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Reviewed By:
(Manager QA)
Sign Date_____

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

7.3 EQUIPMENT SPECIFICATIONS:

7.3.1 CHECK LIST OF PURIFIED WATER DISTRIBUTION SYSTEM:

S.No.	DESCRIPTION OF PURIFIED WATER GENERATION, STORAGE & DISTRIBUTION 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_____

7.4 KEY FUNCTIONALITY

Purpose:

The purpose of this procedure is to demonstrate that the control panel of Purified Water Generation 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_____

7.5 DISPLAY FUNCTIONALITY

Purpose:

The purpose of this procedure is to demonstrate that the control panel of Purified Water Generation 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 (R, Y & B)	To indicate the condition/status of the three phases of power	
IPC indication	To indicate the status of all operational activities in plant	

Inference:

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Reviewed By:
(Manager QA)
Sign& Date_____

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

8.0 CRITICAL VARIABLES TO BE MET:

Parameter	Description
1. Low Level in SMBS dosing tank (LLS-201):	
Test function	Low level in SMBS dosing tank (DT-201)
Procedure	Pull the low level switch from the SMBS dosing tank and record the response
Acceptance criteria	Should give alarm and indication on panel. RO-EDI System will trip.
Remark:	
2. Low Level in ADS dosing tank (LLS202):	
Test function	Low level in ADS Dosing tank (DT-202)
Procedure	Pull the low level switch from the Sodium ADS dosing tank and record the response
Acceptance criteria	Should give alarm and indication on panel. RO-EDI System will trip.
Remark:	
3. Low Level in pH dosing tank (LLS-203):	
Test function	Low level in pHC dosing tank (DT-203)
Procedure	Pull the low level switch from the Sodium pHC dosing tank and record the response
Acceptance criteria	Should give alarm and indication on panel. RO-EDI System will trip.
Remark:	
4. ORP transmitter (ORP-201):	
Test function	High ORP at Feed of RO Pass –I
Procedure	Stop the SMBS dosing pump & allow the high free chlorine water to pass through ORP sensor. **Case I:** Restart the SMBS dosing pump after 1 min. **Case II:** Not to start SMBS dosing pump for 5 mins.

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Parameter	Description
	Allow to pass chlorinated water (less than 0.5 ppm free chlorine) through ORP analyzer and check the response of sensor. **Note: To be checked in Normal Auto mode / Auto flushing Mode.**
Acceptance criteria	**Case I:** Free chlorine will pass through and ORP sensor will sense free chlorine. In turn the ORP value will increase above the set point. This will open the ORP dumping valve AV-202. **Case II:** ORP comes down within the desired limit. Below the set value, it will close the AV-202. Allow the water to feed to the RO. The entire system will start automatically. **Case III:** If the ORP value is high for more than 300 secs. it will trip the plant with alarm & indication on the panel.
Remark:	
5. Low Pressure Switch (LPS-201):	
Test function	Low pressure switch at ROHP-201 (Pass-I) inlet
Procedure	Reset the Low Pressure Switch value in the operating condition above the operating feed pressure of the RO system. Perform this challenged test of Low Pressure switch. After an operation record the response.
Acceptance criteria	This will trip the ROHP-201 with an indication on the panel. entire plant will trip with an alarm & indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing mode.**
Remark:	
6. High Pressure Switch (HPS-201):	
Test function	High pressure switch at ROHP-201 (Pass-I) outlet
Procedure	Reset the High Pressure Switch value in the operating condition below the operating feed pressure of the RO system. Perform this challenged test of High Pressure switch. After an operation record the response.
Acceptance criteria	RO-EDI System will trip with an alarm & indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing mode.**

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Parameter	Description
Remark:	
7. Conductivity Indicator Cum Controller (CIC – 201):	
Test function	High conductivity at RO permeate (Pass-I)
Procedure	Reset the conductivity set point below the actual operating value. **Case I:** Bring it to the normal set point after 1 min. for 4 mins. **Case II:** Allow the set point below the actual reading for more than 5 mins. After an operation record the response.
Acceptance criteria	**Case I:** The dumping valve AV-202should open immediately & dump the permeate water. After the conductivity value is changed to the original pre-set value, after 30 secs of consistent low value below the set point the control value AV-202 automatically close & system starts automatically. **Case II:** After 5 mins of consistent dumping it will trip the Plant with alarm and indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing Mode.**
Remark:	
8. Low Pressure Switch (LPS-202):	
Test function	Low pressure switch at ROHP-202 (Pass-II) inlet
Procedure	Reset the Low Pressure Switch value in the operating condition above the operating feed pressure of the RO system. Perform this challenged test of Low Pressure switch. After an operation record the response.
Acceptance criteria	This will trip the ROHP-202 with an indication on the panel. entire plant will trip with an alarm & indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing mode.**
Remark:	
9. High Pressure Switch (HPS-202):	
Test function	High Pressure Switch at ROHP-202 Discharge.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

Parameter	Description
Procedure	Reset the High Pressure Switch value in the operating condition below the operating feed pressure of the RO system. Perform this challenged test of High Pressure switch. After an operation record the response.
Acceptance criteria	RO-EDI System will trip with an alarm & indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing mode.**
Remark:	
10. Conductivity Indicator Cum Controller (CIC – 202):	
Test function	High conductivity at RO (Pass-II)permeate
Procedure	Reset the conductivity set point below the actual operating value. **Case I:** Bring it to the normal set point after 1 min. for 4 min. **Case II:** Allow the set point below the actual reading for more than 5 min. After an operation record the response.
Acceptance criteria	**Case I:** The dumping valve AV-206 should open immediately & dump the permeate water. After the conductivity value is changed to the original pre-set value, after 30 secs of Consistent low value below the set point the control value AV-206 automatically close & system starts automatically. **Case II:** After 5 mins of consistent dumping it will trip the Plant with alarm and indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing Mode.**
Remark:	
11. Low Flow at RM-206 & RM-207	
Test function	Low flow at RM-206 & RM-207
Procedure	Reset the Low flow rate value in the operating condition above the operating feed flow rate of the EDI system. After an operation record the response.
Acceptance criteria	EDI-101 will trip with indication on panel.
Remark:	

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Parameter	Description
12. Low Pressure Switch (LPS-203):	
Test function	Low pressure switch at EDI-201 inlet
Procedure	Reset the Low Pressure Switch value in the operating condition above the operating feed pressure of the EDI system. Perform this challenged test of Low Pressure switch. After an operation record the response.
Acceptance criteria	This will trip the EDI-201 with an indication on the panel. RO-EDI plant will trip with an alarm & indication on the panel.
Remark:	
13. Conductivity Indicator Cum Controller (CIC – 203):	
Test function	High conductivity at EDI permeate
Procedure	Reset the conductivity set point below the actual operating value. **Case I:** Bring it to the normal set point after 1 min. for 4 mins. **Case II:** Allow the set point below the actual reading for more than 5 mins. After an operation record the response.
Acceptance criteria	**Case I:** The dumping valve FDV-201 should open immediately & dump the permeate water with indication on the panel. After the conductivity value is changed to the original pre-set value, after 30 secs of consistent low value below the set point the control value FDV-201 automatically close & system starts automatically with indication on the panel. **Case II:** After 5 mins of consistent dumping it will trip the Plant with alarm and indication on the panel. **Note: To be checked in Normal Auto mode/Auto flushing Mode.**
Remark:	
14. Low Level in CIP tank (CIPT-201):	
Test function	Low level in CIP tank (CIPT-201)
Procedure	Drain the water in the CIP tank (CIPT-201) such that the level falls down to low level & record the result.

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Parameter	Description
Acceptance criteria	Should give alarm and indication on panel. Should trip the CIP Feed Pump (CIPFP-201).
Remark:	
15. Low temperature at CIP-TT-201:	
Test function	Low temperature at CIP-TT-201
Procedure	Reset the Temperature set value above the current temperature value in CIP loop. After an operation record the response.
Acceptance criteria	Ceramic heater should start.
Remark:	
16. High temperature at CIP-TT-202:	
Test function	High temperature at CIP-TT-202
Procedure	Reset the Temperature set value above the current temperature value in CIP loop. After an operation record the response.
Acceptance criteria	Ceramic heater should stop.
Remark:	
17. Emergency Stop:	
Test function	Emergency stop
Procedure	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.
Acceptance criteria	Emergency stop button shall be locked upon pressed. Purified Water Generation System should stop operation immediately. Audio-visual Alarm shall generate.
Remark:	

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy
- Any other relevant document.

10.0 DEVIATION FROM PRE-DEFINED SPECIFICATIONS, IF ANY:

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11.0 CHANGE CONTROL, IF ANY:

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12.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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13.0 CONCLUSION:

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14.0 RECOMMENDATION:

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14.0 ABBREVIATIONS:

316L	: 316 Low carbon
AI	: Analog Input
AO	: Analog Output
ASTM	: American Society of Testing and Materials
cGMP	: Current Good Manufacturing Practice
CI	: Cast Iron
DI	: Digital Input
DO	: Digital Output
EPDM	: Ethylene Propylene Di Methylene
FDA	: Food & Drug Administration
GA	: General Arrangement
HMI	: Human Machine Interface
ID	: Identification
LPH	: Liter per Hour
mA	: mili ampere
MOC	: Material of Construction
MWC	: Meter Water Column
OD	: Outside Diameter
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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PURIFIED WATER GENERATION SYSTEM

15.0 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)			