



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR
PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM**

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
PURIFIED WATER STORAGE &
DISTRIBUTION SYSTEM**

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



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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 Purified Water Storage & Distribution 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 Purified Water Storage & Distribution System.
- Operate the Purified Water Storage & Distribution 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 Storage & Distribution System. This document will also be followed at the time of installation or removal of any part in the existing Purified Water Storage & Distribution 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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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



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5.0 RE-QUALIFICATION:

Operation Qualification to be re-qualified on:

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

6.0 DESIGN SCHEME

PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

- 5.0 KL SS Purified Water Storage Tank (Half Limpeted)
- Process Loop Pumps (1W + 1 SB)
- 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 Distribution 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.

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.



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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:			
• 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 &		



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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: _____

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 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: _____

Reviewed By:
(Manager QA)
Sign Date _____



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7.3 EQUIPMENT SPECIFICATIONS:

7.3.1 CHECK LIST OF PURIFIED WATER DISTRIBUTION SYSTEM:

S.No.	DESCRIPTION OF PURIFIED WATER 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 _____



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7.4 KEY FUNCTIONALITY

Purpose:

The purpose of this procedure is to demonstrate that the control panel of Purified Water Storage & Distribution 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 Purified Water Storage & Distribution 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 _____



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8.0 OPERATIONAL VERIFICATION:

Parameters	Description
1. HIGH HIGH LEVEL IN PW STORAGE TANK (LT-301)	
Test function	High High Level in PW Storage Tank
Procedure	Do not consume the water in the PWD loop and let the level rise in the PW Storage Tank. As soon as the level of water reaches high high level in PW storage tank record the result.
Acceptance criteria	FDV-201 will close with indication on the panel.
Remark:	
2. HIGH LEVEL IN PW STORAGE TANK (LT-301)	
Test function	High Level in PW Storage Tank
Procedure	Drain the water from PWD loop and let the level falls down in the PW Storage Tank. As soon as the level of water reaches high level in PW storage tank record the result.
Acceptance criteria	FDV-201 will open
Remark:	
3. LOW LOW LEVEL IN PW STORAGE TANK (LT-301)	
Test function	Low Low Level in PW Storage Tank
Procedure	Drain the water in the PW storage tank such that the level in the PW tank falls down to Low Low level. After an operation record the response.
Acceptance criteria	As soon as the Low Low level is achieved in the PW Storage Tank, Process Loop Pump PLP-301/302 will trip with alarm and indication on the panel.
Remark	
4. LOW LEVEL IN PW STORAGE TANK (LT-301)	
Test function	Low Level in PW Storage Tank



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Parameters	Description
Procedure	Fill the water into the PW Storage Tank such that the level in the PW Storage Tank rises up to Low level. After an operation record the response.
Acceptance criteria	Process Loop Pump PLP-301/302 will start.
Remark:	
5. OPTIMUM FLOW IN RETURN LOOP	
Test function	Optimum flow in return loop
Procedure	In operating condition close all ZDV's, After operations record the response.
Acceptance criteria	Flow Transmitter (FT-301) will give signal to PLC & PLC in turn will ensure that minimum velocity of 1.2 m/sec is maintain in the return loop by increasing frequency of pump through VFD.
Remark:	
6. LOW TEMPERATURE IN RETURN LOOP (TT-302)(SANITIZATION MODE)	
Test function	Low Temperature In Return Loop.
Procedure	Operate the PW Distribution system as per the standard operating procedure. Change the set point above the actual value (85 Deg C). After an operation record the response.
Acceptance criteria	AV -301 will be open.
Remark:	
7. HIGH TEMPERATURE IN RETURN LOOP (TT-302) (SANITIZATION MODE)	
Test function	High Temperature In Return Loop.
Procedure	Operate the PW Distribution system as per the standard operating procedure. Change the set point below the actual value (85 Deg C).After an operation record the response.



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Parameters	Description
Acceptance criteria	AV-301 will be close.
Remark:	
8. CONDUCTIVITY TRANSMITTER CUM TRANSMITTER (CIC-301)	
Test function	High conductivity at PWD loop return line.
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-301 should open immediately & dump the permeate water with indication on 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-301 automatically close & system starts automatically with indication on panel. Case II: After 5 mins of consistent dumping it will trip the Process loop pump (PLP-301/302) with alarm and indication on the panel. Note: To be checked in Normal Auto mode/ Auto flushing Mode.
Remark:	
9. PROCESS LOOP PUMP (PLP-301/302)	
Test function	Process Loop Pump working at over load.
Procedure	Reset the VFD load Setting below the actual working load. Operate the PWD system and record the response.
Acceptance criteria	Should Trip the System with an indication and alarm on panel.
Remark:	



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Parameters	Description
10. 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. PWD System should stop operation immediately. Audiovisual Alarm shall generate with indication on the panel.
Remark:	

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
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



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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)			