OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

Signing of this Operational Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Organization	Name	Designation	Signature	Date

CHECKED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

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OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

1. OBJECTIVE

The objectives of this Operational Qualification (OQ) are as follows:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

Following execution of the protocol a summary report will be written and approved. All results, conclusions, exceptions and variances will be addressed and final disposition of the equipment will be stated. Successful completion of this protocol and approval of the summary report will verify that the Purified Water Storage & Distribution System meets all the acceptance criteria and is ready for PQ.

2. SCOPE

This protocol covers all aspects of Operational Qualification for the Purified Water Storage & Distribution System serving the .....; Tablets, Capsules and Liquid Oral Manufacturing Facility. Scope incorporates qualification of all components starting after Valve V44 (refer P & ID Orion 4000) up to all user points, consisting of Purified Water Storage Tank, Sanitary Grade Pumps, UV Unit, Point of Use and Inter connecting Piping inside battery limit as marked in P&I Diagram for Storage & Distribution System.

This protocol will define the methods and documentation used to qualify the Purified Water Storage & Distribution System for OQ. Successful completion of this protocol will verify that the Purified Water Storage & Distribution System meets all acceptance criteria and is ready for Performance Qualification.

3. RESPONSIBILITIES

All work is to be performed under .....over site and according to ..... approved procedures.

<u>Engineering Validation Personnel</u>

The following are the responsibilities of Engineering Validation Personnel:

- Preparation, Review and submission of OQ Protocol.
- Ensures that the protocol is in compliance with current ..... policies and procedures.
- Ensures that the content is sufficient, clearly defined technically sound and accurate.
- Ensures compliance with design specifications.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

Validation Personnel

The following are the primary responsibilities of the .....Validation Personnel:

- Overall cGMP compliance for OQ
- Review and Pre-Approval of OQ Protocol
- Execution of this OQ protocol
- Document Control of OQ Protocol until such document is completed, approved and after.
- Regulatory Compliance Review of the completed OQ Protocol
- Review and Approval of the executed OQ Protocol.

4. SYSTEM DESCRIPTION

Purified Water from Purified Water Generation System is used as feed to this system. Purified Water is stored in SS 316L storage tanks. This tank is designed for full vacuum and is fully drainable. The tank is having the internal finish of 240grit and surrounded by limpet coil and jacket. Chilled water at 5.5°C is circulated through limpet coil to maintain temperature of Purified Water at 15-27°C. Purified water is heated to 80°C + 5 °C using steam in Jacket of Purified Water Storage Tank during sanitization. Hot Water is circulated at 80°C throughout the distribution loop covering all the user plants.

Purified Water is distributed through SS 316L pipes having 2" diameter. These pipes have 0.5 Ra internal finishes and have slope of 1:100 to make the system fully drainable. Purified Water before being distributed to different user points is subjected to Ultra Violet light to have microbial control.
Purified Water is pumped through sanitary grade Centrifugal Pumps. Casing and Impeller of these pumps are in SS316L. One Cold standby pump is provided for the system. Pump has been provided with VFD and with a closed loop control from flow meter installed at the return. The control logic is to maintaining a minimum velocity of 1m/sec by changing speed of pump as the demand increases or reduces.

Non-Metallic parts like gaskets, 'O' rings, diaphragms coming in contact with Purified Water is of food grade quality.

Purified Water is re-circulated through return loop, sprayed into the Storage Tank through 360° shadow free spray ball. Purified Water shall be maintained between 15-27°C and its velocity should not fall below acceptable limit that is 1m/sec in return loop. The distribution network shall not have dead leg > 6d (as per Article 8.7.1.6 of ISPE Base Line, Volume-4, and Water & Steam Systems). All the joints are connected with triclover clamps. The system does not have any direct connection to drains or sewers to prevent bacteria entry into the system. Sampling points are provided after each equipment and in return loop.
Associated System components comprise:

- **Control System:** The Purified Water Storage and Distribution System is controlled and monitored via a Siemens PLC (Programmable Logic Controller) and Industrial type Man Machine Interface (MMI), with an external PLC Interface to a printer. All the major parameters including Alarms, and Valves will be through control panel of the PLC.

- **Safety system:** The following Safety systems are incorporated:
    - Emergency push button is provided
    - *Mechanical guard for all rotating parts are provided*
    - The system is checked for any leakages present
    - Electrical panels is properly grounded with no un sec used joints
    - Double earthing is provided for all electrically operated equipment
    - Overload relay for motors provided in pump feeder in MCC
    - Noise pollution is under 80db at 1M from source.
    - Tagging and naming of all electrical wires and pneumatic tubing is done
    - Drain and effluent from the system is complying to local code of practice

5. DOCUMENTATION REQUIREMENTS

The OQ File should include:

- This OQ Protocol.
- Any laboratory test results or their referenced location.
- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

6. DATA COLLECTION

All personnel shall have suitable documented training or experience.

All approvals shall be made in *BLUE* ink.

All data entry shall be made in *BLUE* ink.

All corrections to this Protocol, which are not retyped, are to be made in *BLUE* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.
After performing the qualification tests, collect all relevant printouts and certificates and retain for inclusion in the OQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Appendices* and to be listed in *Section 13. List of Appendices*.

7. CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the .....project Change Control Procedure.

Change Control Forms raised during the execution of this OQ will be filed along with the protocol. An assessment will be made for each change to determine whether or not any re-validation is required.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

8. PRE-QUALIFICATION REQUIREMENTS

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

System Pre-requisites

No.	Description of Pre-requisite	Completed Yes or No	Verified By	Date
1	Verify that the IQ of the Purified Water Storage & Distribution System has been executed and approved. IQ Protocol Document No: IQ /U/PWD-01/00	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Purified Water Storage & Distribution System has been executed and approved.	Yes/No*		
3	Verify that the safety walk through has been completed and that the system is safe to use.	Yes/No*		
Verify that authorised drafts of the following procedures (SOP / PMI) relevant to operation of the Purified Water Storage & Distribution System are available.				
4	SOP-Purified Water Storage & Distribution System Operation	Yes/No*		
5	SOP-Purified Water Storage & Distribution System Maintenance.	Yes/No*		
6	SOP Purified Water Storage & Distribution System Cleaning /Washing	Yes/No*		
7	SOP-Purified Water Storage & Distribution System Calibration.	Yes/No*		

Note:- * -Circle one, which is appropriate.

9. TESTS AND CHECKS

SOP Verification

9.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Purified Water Storage & Distribution System.

9.1.2 Method

Obtain a controlled copy of each SOP referenced within section 9.1.4. During the course of OQ testing, perform each operation according to the instruction indicated within the appropriate SOP. Mark with a highlighter pen each instruction or statement within the SOP which is verified and in accordance with the actual practice. Write any differences from actual practice in red ink on the copy of the SOP. On completion, write "Operational Qualification - SOP Verification" on the marked-up copy of the SOP, sign & date it and attach as an appendix to the OQ protocol together with any other raw data such as printouts. Ensure all SOP's identified in Section 9.1.4 are evaluated and checked.

9.1.3 Acceptance Criteria

At the completion of OQ testing, all standard operating procedures referenced within section 9.1.4 will be annotated to correctly reflect the applicable method instruction(s) required to obtain intended operation or function result.

9.1.4 Results

Enter the SOPs into the table below and verify that they have been evaluated and checked. Incorporate the marked up SOPs as an appendix to the OQ report together with any other raw data such as printouts

SOP Number	SOP Description	SOP accurate after check [Y/N}	Initial / Date
	Purified Water Storage & Distribution System Maintenance.		
	Hot water sanitization of Purified Water Distribution System		
	Sensitization of Purified Water Storage Tank and Vent filter		
	Calibration of Temperature indicator		
	Calibration of Flow indicator		
	Calibration of Conductivity indicator		
	Calibration of Conductivity sensor		

Comments:
Signed: Date

Reviewed by		Date	

Digital Input / Output (I/O) Test

9.1.5 Objective

To verify that PLC digital Inputs and Outputs (I/Os) are connected to the correct field device.

9.1.6 Method

Digital input/output checks have been carried out as part the PLC Validation. Ensure that all tasks have been completed and signed off as correct.

At the time of testing, have available a copy of the following documents:

- Software Design Specification for the Purified Water Storage & Distribution System.
- Hardware Acceptance Test Specification for the Purified Water Storage & Distribution System.

With a copy of the Hardware Acceptance Test Specification, test 10% of all Digital I/Os in accordance with the method statement described in the document. Record details of individual I/Os re-tested on a check sheet and verify that the I/O has passed or failed.

If there are no failures when testing 10% of the I/Os, then I/O testing is complete. Record results in section 9.2.4. Should there be a failure of one or more I/Os proceed to re-test 50% of all I/Os in the manner described above. If no failures are found while checking 50% of the I/Os, then I/O testing is complete. Record results in section 9.2.4. If there are one or more failures while testing 50% of the I/Os, proceed to test 100% of the I/Os in the manner described above.
Should less than 100 Digital I/Os be apparent for the system, re-test a minimum of ten I/Os. If less than 10 Digital I/Os are apparent, re-test all the I/Os.

Note: Only test I/Os that will not cause any physical/ structural damage to the system as a result.

9.1.7 Acceptance Criteria

PLC must show that all field devices operate and communicate correctly with the control system in agreement with the electrical schematics. Therefore, verify that all testing was witnessed, completed and signed off as correct.

Where Digital I/Os have been re-tested, verify that all field devices operate and communicate in accordance with the control system and in agreement with associated electrical schematics.

9.1.8 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Verify Digital Input/Output Tests have been Completed.	Tests have been witnessed, completed and signed off as correct.			
Test the digital I/Os as described in "Section 9.2.2 Method".	Field devices operate and communicate correctly with the control system in agreement with the electrical schematics.			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

Analogue Input Test

9.1.9 Objective

To verify that PLC Analog Inputs are connected to the correct field device.

9.1.10 Method

Analog input and calibration checks have been carried out as part the PLC Validation. Ensure that all tasks have been completed and signed off as correct.
At the time of testing, have available a copy of the following document:

- *Software Design Specification for the Purified Water Storage & Distribution System*.
- *Hardware Acceptance Test Specification for the Purified Water Storage & Distribution System*.

With a copy of the PLC document, re-test 10% of all Digital Inputs in accordance with the method statement described in the PLC. Record details of individual inputs re-tested on a check sheet and verify that the input has passed or failed.

If there are no failures when testing 10% of the inputs, then input testing is complete. Record results in section 9.3.4. Should there be a failure of one or more input proceed to re-test 50% of all inputs in the manner described above. If no failures are found while checking 50% of the inputs, then input testing is complete. Record results in section 9.3.4. If there are one or more failures while testing 50% of the inputs, proceed to test 100% of the inputs in the manner described above.

Should less than 100 Analog inputs be apparent for the system, re-test a minimum often inputs. If less than 10 Analog inputs are apparent, re-test all the inputs.

Note: Only test inputs that will not cause any physical/ structural damage to the system as a result.

Ensure that all instruments or equipment used to conduct this test are calibrated. Attach copies of calibration certificates as appendices to this protocol and record details as necessary in Section 8.2.

9.1.11 Acceptance Criteria

PLC document data must demonstrate that all field devices operate and communicate in accordance with control system function and be correctly defined by the electrical schematics. Analogue input values must be correct and calibrated within specified tolerance when displayed on the Operator Interface. Therefore, verify that all testing was witnessed, completed and signed off as correct.

Where Analog inputs have been re-tested, verify that all field devices operate and communicate in accordance with the control system and in agreement with associated electrical schematics.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.12 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Verify Analogue Input Tests have been Completed.	Tests have been witnessed, completed and signed off as correct.			
Test the digital Inputs as described in "Section 9.3.2 Method".	Field devices operate and communicate correctly with the control system in agreement with the electrical schematics.			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

System Security Test

9.1.13 Objective

To verify that access to system programs and data are protected in an adequate manner.

9.1.14 Method

Follow instructions in the Test Method column in section 9.4.4 to test security of the system. Record all observations in the actual results column in section 9.4.4 and attach any raw data printouts as an appendix to this protocol.

9.1.15 Acceptance Criteria

Access to control system and software is to authorised personnel only. Specific acceptance criteria for each test are provided in section 9.4.4.

9.1.16 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
<< enter test methods for testing in-built security access to the control system (level 0, level 1, level 2, level 8 and level 9 – refer Functional requirement specification and FAT report>>	<< Enter expected result of each test >>			
Attempt to access PLC.	Physical restriction by lock to an unauthorised user is in place.			
Access to the back-up software.	Physical restriction by lock to an unauthorised user is in place.			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

System Start-Up and Shutdown Test

9.1.17 Objective

To verify that the system components will power-up and start as defined by the design documentation.

9.1.18 Method

Follow instructions in the Test Method column of section 9.5.4 to test the start-up and shutdown of each system component. Obtain approval from the Production, Electrical and Mechanical Departments (where applicable) prior to this test and attach the approval slip as an appendix to this protocol. Record all observations in section 9.5.4 and attach any raw data printouts as an appendix to this protocol.

9.1.19 Acceptance Criteria

All Start-up and Shutdown functions operate correctly as specified in the following document:

- *System Operating and Maintenance Manual* Purified Water Storage & Distribution System *: <<Document Ref>>>*

Specific acceptance criteria for each test are provided in the tables in section 9.5.4.

9.1.20 Results

Shutdown Procedure

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
While the system is operating, cease operation by assigning the following mode on the Man Machine Interface (MMI):				
Stop UV Sterilizer (UV –201)	Indication of IM-202 drops to zero IN MMI			
Stop Pump (P-201)	Indication in MMI thru VFD, PT-203 reading drops to zero, FT-201 reading drops to zero			
Force close valve no. V44 thru PLC of Purified Water Generation	Indication closure on MMI			
All manual isolation valves for utilities to be closed. Verify through visual inspection	Ensure valves are physically closed.			
Power-Up and Start Test				
Open all manual isolation valves for utilities. Check through visual inspection.	Valves are open physically.			
Open valve no. V44 thru PLC of Purified Water Generation	Indication valve open on MMI			
Start Pump (P-201)	Indication in MMI thru VFD, PT-203 gives reading , FT- 201 gives reading			
Start UV Sterilizer (UV –201)	Indication of IM-202 rises			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

Operator Data Entry Test

9.1.21 Objective

To verify system response following Operator Data Entry and to ensure that the system will only accept approved inputs and that all other inputs are rejected in a controlled manner.

9.1.22 Method

Follow the instruction within the test method column of section 9.6.4 to test the data entry of the system. Record all observations in the actual results in section 9.6.4 and attach any raw data printouts as an appendix to this protocol.

Ensure that upon test conclusion, all parameter set points are returned to normal operating status.

9.1.23 Acceptance Criteria

Operator inputs with limits / formats associated with them will accept values as stated in column “System accepts Input as Valid”. Entered value or format stated in column “System rejects Input as invalid” will be rejected by the system.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.24 Results

System Variable	Limits		Value Smaller than Min	Value Greater than Max	Alpha Key Input	Expected Result Met?	
	Min	Max				Yes/No	Initial & Date
Expected Result	**System accepts Input as Valid**		**System rejects Input as Invalid**				
CT-201	0	1.1	-1	1.2	A/&		
CT-202	0	1.1	-1	1.2	A/&		
FT-201	1000	12000	999	12001	A/&		
TT-201	0	30	-1	31	A/&		
TT-202	0	85	-1	86	A/&		
PT-201	0	3	-1	4	A/&		
PT-202	0	3	-1	4	A/&		
PT-203	0	3	-1	4	A/&		
LT-201	0	3000	-1	3001	A/&		

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

System Functionality Tests

9.1.25 Objective

To verify Purified Water Storage & Distribution System components functionality.

9.1.26 Method

Prior to this test, power up and start-up each component as described in Section 9.5.4: *Power Up and Start Test.* Operate each item as described in Section 9.7.4 to test the functionality of the system. Record all observations in the Actual Results column in Section 9.7.4.

9.1.27 Acceptance Criteria

All aspects of control for individual components integrated within the Purified Water Storage & Distribution System shall function as specified in the expected results column in Section 9.7.4.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.28 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switching on the Power and Utilities to the System				
1. Switch on the power & utilities to Purified Water Storage & Distribution System	Purified water storage system starts in step operation.			
2. Monitor and Log the readings.	Log the following readings: 1. Voltage. 415 ± 10 % Volts 2. Compressed air pressure – 6 bar. 3. Steam Pressure – 3.1 bar at 130 °C 4. Chilled Water - 2.5 Kg/cm^2 at 5.5 °C			
Storage Tank				
1.Visual inspection of the Tank after filling with water.	No leakages across tank.			
2.Heating of Vent Filter through electric tracer. Measure temperature through thermometer	Temperature to be in range 0 - 300			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.7.4 Results (cont'd)

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Sanitary Grade Pump				
1. Visual inspection to see leakage and pump rotation on staring pump.	Pump rotation to be anticlockwise. No visual leakages across pump.			
2. Stop Pump P-201	Indication in MMI for stop and alarm. PT 203 reading drops to zero			
3. Acknowledge alarm and start Pump P-201	Inidication in MMI for pump running and PT 203 reading shall be in range.			
4. Change flow rate of Pump P 201 by opening some of user valves.	Frequency of Pump increases as indicated in MMI.			
UV Unit				
1. Measure UV intensity reading of IM – 202	Reading to be in range of 0 – 30 W/m^2			
2. Force condition of High UV housing intensity.	UV trips and alarm generated by PLC.			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

System Alarm and Interlocks Test

9.1.29 Objective

To verify that operation of system alarms and interlocks are functioning correctly.

9.1.30 Method

Purified Water Storage & Distribution System Alarm Tests have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document - <<Document Ref>>>. Ensure that all tasks have been completed and signed off as correct. State this in the section below and refer to the relevant supporting documentation in the Actual results column.

With a copy of the SAT document <<Document Ref>>>. and relevant sections of the Software Design Specification for the Purified Water Storage & Distribution System , <<Document Ref>>>, re-test 10% of all alarms in accordance with the method described in the SAT. List down the names of individual alarms and interlocks re-tested on a check sheet. Verify on the check sheet that the alarm/ interlock has passed or failed.

If there are no failures when testing 10% of the alarms, then alarms testing are complete. Record results in section 9.8.4. Should there be a failure of one or more alarm proceed to re-test 50% of all alarms in the manner described above. If no failures are found while checking 50% of the alarms, then alarms testing are complete. Record results in section 9.8.4. If there are one or more failures while testing 50% of the Alarms, proceed to test 100% of the Alarms in the manner described above.

Note: Only test the alarms / interlocks that will not result in any physical/ structural damage to the system as a result.
Ensure that all instruments or equipment used to conduct this test are calibrated. Attach copies of calibration certificates as an appendix to this protocol, and record details as necessary in Section 8.2.

Attach a copy of the alarms and Interlocks test check sheet as an appendix to the protocol. Record all observations in the Actual Results in section 9.8.4 and attach any raw data printouts to the alarms and Interlocks test check sheet.

9.1.31 Acceptance Criteria

SAT document must show that the system alarms/ interlocks activate in the correct situation and with the correct effect.

Alarm / Interlock retesting must activate in the correct situation and with the correct effect as described in the SAT document.

System cannot be started when critical alarms are activated.
Record of alarms/interlocks testing check sheet is attached in the appendix

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.32 Results

Item	Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
LIAH 201 L of AHH	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Storage Tank High" the V 44 (Inlet from Purified Water Generation) closes			
LIAL 201 L of ALL 201	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Storage Tank Low" the P -201(Pump) Trips			
PIAL 203	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Pump Pressure Low" the KV 202 Closes			
CIAH 201	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Conductivity at tank outlet High"			
CIAHH 201	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Conductivity at tank outlet High" and actuates dump valve KV 203.			
FIARL 201	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Flow at Return loop Low "			
CIARH 202	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Conductivity at Return loop High"			
CIARHH 202	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Conductivity at Return loop High" and actuates dump valve KV 204.			
TICL 202	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Purified Water Temperature at Return loop High" and actuates valve KV 205.			
PIAL 201	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Steam Pressure Low"			
PIAL 202	(Input the test method to trigger the alarm)	The operator station (MMI) shows, "Chilled Water Pressure Low"			

Equipment Operated by		Date	

Comments:			
TICL 202 to indicate Low alarm during Sanitization only.			
Signed:	Date:		
Reviewed by		Date	

System Emergency Shutdown Stop

9.1.33 Objective

To verify that the emergency stop function activation shuts down the system in an appropriate manner.

9.1.34 Method

Ensure system is running under normal operating procedures. Press the emergency stop button and follow instructions in the Test Method column in section 9.9.4. Record all observations in the Actual Result column in section 9.9.4 and attach any raw data printouts as an appendix to this protocol.

9.1.35 Acceptance Criteria

Component comprising the system shut down in a safe and controlled manner when the emergency stop button is pressed. All pumps and motors will trip. An alarm condition is registered with audible alarm.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.36 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial /Date
Press Emergency Stop Button while the system is running in normal operating mode	The system shuts down in a safe and controlled manner. 1. "Emergency stop tripped" alarm displayed. 2. Audible alarm sounds 3. Stop UV Sterilize 4. Stop Pump 5. Isolate all utilities. 6. Force Close V-44 from PW Generation PLC.			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

System Power Failure and Recovery Test

9.1.37 Objective

To ensure that system integrity is maintained in the event of power loss, that the system operates in accordance with specified acceptance criteria during failure and that the system can be recovered back to a satisfactory operational state without the loss of data.

9.1.38 Method

Perform a simulated power loss while the systems operating normally without any faults. Verify the capability of the system to safely recover and resume normal operation. Verify that the system is able to retain the original program without data corruption. Also, verify that the system can prevent loss or corruption of stored data.

Follow instructions in the Test Method column in Section 9.10.4. Record all observations in the Actual Results column in section 9.10.4 and attach any raw data printouts as an appendix to this protocol.

9.1.39 Acceptance Criteria

Upon loss of power the system shuts down safely without causing damage to equipment components and can automatically restart following a power failure event without the need for application of additional resetting procedures.
The system is able to retain the original program upon a loss of power.

The system is able to prevent the loss or corruption of stored data during a power failure.

9.1.40 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Copy the list of set parameters from the MMI at the Configuration Menu before power failure test in Section 9.10.4.1 'Parameter Settings'. Perform a simulated power loss while the system is operating normally without any faults.	The system will automatically restart upon restoration of electrical power. The system will choose from which phase the plant has restart, depending on the parameters conditions at the power ON moment.			
Restore electrical power to the system.	The system steps through the start-up and normal operation phases identical to start-up test.			
After the restoration and recovery of electrical power, copy the list of set parameters from the MMI at the Configuration Menu in Section 9.10.4.1 'Parameter Settings'. Check the set parameters value before and after power failure. Verify that the system is able to retain original program without data corruption in case of power failure.	Parameters settings before and after power failure are the same.			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.10.4.1 Parameter settings

System Variable	Prior to Power Failure	Following power restoration	Initial / Date
LT 201			
TT 201			
TT 202			
DT 203			
Flow			
Intensity			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

Filter Integrity Test

9.1.41 Objective

To verify that installed filters have been integrity tested, and that certification remains valid within the period set forth for operational use.

9.1.42 Method

Review filter integrity test documentation for filters listed in section 9.11.4. Verify that the method used for testing was in accordance with .....procedure, that test results conform to specifications contained therein, and that certification encompasses the period intended for operational use of the system.

Attach copies of integrity test printouts / reports for each filter and record results in Section 9.11.4. Record details of associated test equipment section 8.2 'Test Equipment Calibration' and attach calibration certificate copies as an appendix to this protocol.

9.1.43 Acceptance Criteria

Test methods comply with ..... procedure 'Integrity Testing of Filters'.

All filters have been issued with an approved integrity test certificate that is valid for the period of operational use.

9.1.44 Results

Filter Installation location/description and Filter Tag No	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Purified Water Storage Tank / Vent Filter / VF 201	PWS Tank / Vent Filter / VF 201			

Comments:
Signed: Date:

Reviewed by		Date	

Operator Interface and Screen Graphics Testing

9.1.45 Objective

To verify the operation of all push buttons, touch buttons, switches and screen graphics associated with the Purified Water Storage & Distribution System .

9.1.46 Method

Verify that all push buttons, touch buttons and switches and screen graphics operate as defined in the tables. Document the results of the test in the table below. Record the results in section 9.12.4 of this protocol.

Verify and mark-up a copy of the following operator screens and attach the copy to the protocol

- Main Menu
- Set point Screen #1
- Set point Screen #2
- Set point Screen #3
- Set point Screen #4
- PID Set-up Screen #1

Append the marked up screen graphics printouts in appendix.

9.1.47 Acceptance Criteria

The push buttons touch buttons and switches operate as defined in the tables. The screen graphics appear as defined in the table.

The actual results meet the expected results as defined in the test table(s) provided.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.48 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Control panel:				
Alarm sounder reset: Generate an alarm and press the Alarm sounder reset	The Audible alarm silences, but raised alarm is still active.			
Reset Fatal alarm button: Generate an alarm and press the Reset Fatal alarm button when the alarm condition has been lifted.	The alarm is reset and the alarm disappears from the alarm status 'active alarms' screen.			
Display or print each of the screens containing critical data, from the system MMI. Verify the screens against those specified. Append printouts to this protocol.	The screens printed or displayed from the system, accurately represent the screens specified by the vendor documentation			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

Valve Operational Test

9.1.49 Objective

To ensure that valves located at throughout the Purified Water Storage And Distribution system operate correctly and can be accessed safely.

9.1.50 Method

Locate each valve listed in Section 9.13.4. Perform the test by manually opening and closing the valve. Verify that all valves can be accessed safely and that each valve can be fully opened and closed. Record results following testing in section 9.13.4.

9.1.51 Acceptance Criteria

Each valve can be accessed safely.
Each valve can be operated at full open and full closed positions.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.52 Results

Valve Check	Expected Result	Valve Tag No	Actual Result	Acceptable [Y/N]	Initial / Date
Verify that each valve can be assessed safely. Verify that each valve operates and seals correctly.	Valve can be accessed safely. Valves operate and seal correctly.				

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.13.4 Results (cont'd)

Valve Check	Expected Result	Valve Tag No	Actual Result	Acceptable [Y/N]	Initial / Date
Verify that each valve can be assessed safely. Verify that each valve operates and seals correctly.	Valve can be accessed safely. Valves operate and seal correctly.				

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.13.4 Results (cont'd)

Valve Check	Expected Result	Valve Tag No	Actual Result	Acceptable [Y/N]	Initial / Date
Verify that each valve can be assessed safely. Verify that each valve operates and seals correctly.	Valve can be accessed safely. Valves operate and seal correctly.				

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

Confirmation of Critical Parameter and Full Function Testing

9.1.53 Objective

To confirm that the critical parameter and full function of the Purified Water Storage & Distribution System are as defined below:-

- Low pressure at the outlet of Pump close valve KV 202
- High Conductivity at the outlet of tank to actuate dump valve KV 203
- High Conductivity at the return loop to actuate dump valve KV 204
- Temperature at the return loop to regulate valve KV 205 during sanitization only.
- Temperature of purified water storage tank to regulate valve KV 201 & KV 205 during normal operation.
- Flow at return loop to control RPM of the pump thru VFD.

9.1.54 Method

Follow the test methods described in section 9.14.4 for various parameters under test.
Record the observation in 9.14.4 actual results column.
Attach supporting documents, as applicable, in the appendix.

9.1.55 Acceptance Criteria

The critical operational parameters and full function testing on the Purified Water Storage & Distribution System has been identified and completed satisfactorily.

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.56 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Low pressure at the outlet of Pump close valve KV 202				
Monitor and log Pressure thru PIA 203	PIA 203 reading			
High Conductivity at the outlet of tank to actuate dump valve KV 203				
Monitor and log Conductivity thru CIA 201	CIA 201 reading			
Monitor and log Conductivity thru CIA 202	CIA 202 reading			
Temperature at the return loop to regulate valve KV 205 during sanitization only.				
Monitor and log Temperature thru TIC 202	TIC 202 reading			
Temperature of purified water storage tank to regulate valve KV 201 & KV 205 during normal operation.				
Monitor and log Temperature thru TIC 201	TIC 201 reading			
Flow at return loop to control RPM of the pump thru VFD.				
Monitor and log Flow thru FT 201	FT 201 reading			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

Loss of Utilities

9.1.57 Objective

To verify the loss of utilities supplies will not affect or damage the Purified Water Storage & Distribution System and that the subsequent return of any failed utility does not pose a threat to the system, the system's operator and the product quality.

9.1.58 Method

- **Steam Supply to the Purified Water Storage & Distribution System**
  Run the Purified Water Storage & Distribution System in normal operation.
  Isolate the supply of Steam to the system. Record the system's reactions and any alarms generated in the result table below.
  Reinstate the supply of Steam to the Purified Water Storage & Distribution System and record the systems reactions in the result table 9.15.4 as the system returns to normal operation
- **Compressed Air Supply to the Purified Water Storage & Distribution System**
  Run the Purified Water Storage & Distribution System in normal operation.
  Isolate the supply of compressed air to the Purified Water Storage & Distribution System. Record the system's reactions and any alarms generated in the result table below.
  Reinstate the supply of compressed air and record the systems reactions in the result table 9.15.4 as the system returns to normal operation

- **Chilled Water Supply to the Purified Water Storage & Distribution System**
  Run the Purified Water Storage & Distribution System in normal operation.
  Isolate the supply of chilled water to the Purified Water Storage & Distribution System. Record the system's reactions and any alarms generated in the result table below.
  Reinstate the supply of chilled water and record the systems reactions in the result table 9.15.4 as the system returns to normal operation

9.1.59 Acceptance Criteria

The Purified Water Storage & Distribution System shall raise an alarm and revert to the scenario's listed in the results section below on the isolation of:

- Steam Supply
- Compressed air
- Chilled water

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

9.1.60 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Shut off the Steam Supply to the Purified Water Storage & Distribution System by closing valve. Record the system's reactions in the actual result column.	Alarm is generated			
Supply to the Purified Water Storage & Distribution System is restored by opening valve. Record the system's reactions in the actual result column.	System is restored			
Turn off compressed air supply to the Purified Water Storage & Distribution System by closing valve. Record the system's reactions in the "actual result" column.	"Compressed air flow low" alarm activates.			
	All actuated valves fail-safe			
	System shuts down			
Restore compressed air supply to the Purified Water Storage & Distribution System by opening valve. Record the system's reactions as the system returns to normal operation.	"Compressed air flow low" alarm resets.			
	System reverts to normal status.			
Shut off the Chilled Water Supply to the Purified Water Storage & Distribution System by closing valve. Record the system's reactions in the actual result column.	Alarm is generated			
Supply to the Purified Water Storage & Distribution System is restored by opening valve. Record the system's reactions in the actual result column.	System is restored			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

9.16 Automation Interface Tests

9.16.1 Objective

To verify that the interface between the control system and other automation is as defined.

9.16.2 Method

Follow the instructions in the Test Method column in the table to test the interface between the control system and other automation. Record all observations in the Actual Results section of the table.

9.16.3 Acceptance Criteria

The interface between the control system and other automation must be as defined in the expected result column within the table

9.16.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Disconnect the MMI communication cable.	PLC will display "Communication Error".			

Equipment Operated by		Date	

Comments:
Signed: Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

10. CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
9.1	SOP Verification		
9.2	Digital Input & Output Test		
9.3	Analog Input Test		
9.4	System Security Test		
9.5	System Start-Up and Shutdown Test		
9.6	Operator Data Entry Test		
9.7	System Functionality Test		
9.8	Alarm and Interlocks Test		
9.9	Emergency Shutdown Test		
9.10	Power Failure and Recovery Test		
9.11	Filter Integrity Test		
9.12	Operator interface and Screen Graphics Testing		
9.13	Valve Operational Test		
9.14	Confirmation of Critical parameter and full function testing		
9.15	Loss of utilities		
9.16	Automation Interface test		

Comments:	
Signed:	Date:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

11. VARIANCE SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP "Handling of Deviations". Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the OQ File.

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Variance No.	Variance Title	Status

Comments:
Signed: Date:

Reviewed by		Date	

12. REFERENCES

The Principle Reference is the following

- Master Validation Plan.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol 2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, *Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs*, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, *Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals*, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, *Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation*, October 1999.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- "Handling of Deviations".
- "Change Control Procedure".

13. LIST OF APPENDICES

Appendix No.	Document Title

14. SUMMARY

OPERATIONAL QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

15. APPROVALS

The following approvals signify that the OQ is complete and acceptable and that the system is ready for PQ Execution.

EXECUTED BY:

Organization	Name	Designation	Signature	Date

REVIEWED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date