INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER STORAGE & DISTRIBUTION SYSTEM

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

Signing of this Installation 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

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

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INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

1. OBJECTIVE

The objective of this Installation Qualification (IQ) is as follows:

- To verify that the Purified Water Storage & Distribution System in ……. has been installed in accordance with the set acceptance criteria and meets cGMP requirements.
- To verify that there is sufficient and accurate information to operate and maintain the system reliably and reproducibly.
- To verify that the requirements specified at the time of purchase are met in the delivered and installed item. Purchase Order and Equipment Specifications have been used to prepare this Protocol. Confirmation of the installed system to pre-determined specifications will verify that user requirements have been met.

2. SCOPE

This protocol covers all aspects of Installation Qualification for the Purified Water Storage & Distribution System serving the …….. Scope incorporates qualification of all components starting after Valve V44 (refer P&ID Orion) 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 IQ. Successful completion of this protocol will verify that the Purified Water Storage & Distribution System meets all acceptance criteria and is ready for Operational Qualification.

3. RESPONSIBILITIES

All work is to be performed under ……..oversight and according to …… approved procedures.

Jacobs Engineering Validation Personnel

The following are the responsibilities of Engineering Validation Personnel:

- Preparation, Review and submission of IQ 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.

Validation Personnel

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

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

- Review and Approval of the executed IQ Protocol.

4. SYSTEM DESCRIPTIONS

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, 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 IQ File should include:

- This IQ Protocol
- Any change control actions that may have occurred during the qualification activities.
- Any deviations, 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.
When appropriate, Drawings shall be marked up according *to as fallowing*

- System checked and conforms to the Drawing: *YELLOW* highlighter
- System checked and does not conform to the Drawing: *RED* highlighter and notes in *RED* pen.
- Personnel who mark up the drawing shall initial and date it.

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 checks, collect all relevant printouts and certificates and retain for inclusion in the IQ File. If more Data Sheets or Deviation Sheets are required, they are to be attached to this Protocol as *Annexures* and to be listed in *Section 13. List of Annexures*.

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 IQ will be filed with the protocol. An assessment will be made to check whether any re-validation is required by ……..before the change request is closed out.

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER 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 IQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

Test	Test Date	Documentation [Title, Rev.]	Documentation Location	Complete [Y/N]	Date/ Initials
FAT					
Commissioning / SAT					

Comments:

Reviewed by		Date	

9. TESTS AND CHECKS

The following tests and checks are to be completed for IQ of Purified Water Storage & Distribution System. After completion of this section, fill the *Checklist* in *Section 10*.

9.1 Drawing Verification

9.1.1 Objective

To verify that relevant drawings of the equipment are available and current.

9.1.2 Method

Examine whether the specified drawings of equipment are available and current. Ensure Title, Revision No., Originator and Document Location are recorded in *Section 9.1.4 Data*. Record any deviation / non-conformance as described in *Section 11. Deviation Sheet.*

9.1.3 Acceptance Criteria

Drawings must be of the latest version approved and filed correctly.

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.1.4 Data

Reference Engineering Drawings [Title, No., Originator (Company)]	Drawings Rev. No. & Issue Date	Document Location	Acceptable [Y/N]	Initial / Date
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-01, M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-02 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-03 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-04 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-05 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-06 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-07 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-08 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-09 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-10 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-11 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-12 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-13 M/s Christ Nishotech Water System Pvt. Ltd.				
Isometric Drawing for Storage & Distribution System, Dwg No. CW108-07-14 M/s Christ Nishotech Water System Pvt. Ltd.				
P&I Diagram for Storage and Distribution System				

Comments:

Reviewed by		Date	

9.2 Documentation Verification

9.2.1 Objective

To verify that sufficient documentation exists to operate and maintain the system reliably and reproducibly.

9.2.2 Method

Verify that Purified Water Storage & Distribution Turnover Package contains the following documents where deemed appropriate. Identify the sub-folder index of each available document. Examine whether the available documents are as listed in *Section 9.2.4 Data*. Fill detailed information of the Obligatory documents, such as title, revision number, and location in *Section 9.2.4.1 Document Details*.

Provide title and document number for SOPs in *Section 9.2.5 SOP List*.

Report any deviations / non- conformances as described in *Section 11. Deviation Sheet*.

9.2.3 Acceptance Criteria

All obligatory documents must be available in a current status. Where relevant, documents must be approved as per ……..procedure.

9.2.4 Data

When a specified document is located within another document, cross-refer to the main document at the Comment Column.

Document	Not required	Obligatory	Optional	Available [Y/N]	Comment	Initial / Date
General Documentation						
Purchase Orders		√				
Vendor Offer			√			
URS		√				
Design Descriptions		√				
Engineering Drawings List		√				
Factory Acceptance Tests		√				
Commissioning / SAT Documentation		√				
Operation Manuals		√				
Authority Certificate			√			
Certificates of Conformity		√				
Mechanical Documentation						
Mechanical Parts List		√				
Welder Qualifications		√				
Weld / Coupon Logs		√				
Boroscope Testing		√				
Pressure Test Certificate		√				
Pneumatic Diagrams		√				
Maintenance Manuals		√				
Material Specifications		√				
Product contact material certificate		√				
Electrical Documentation						
Electrical Parts List		√				
Electrical Diagrams / Relay diagram		√				
I/O Listing		√				
Instrument List		√				
Instrument calibration certificates		√				

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.2.4.1 Document Details

Document Title / No./ Originator (Company)	Revision No. / Issue Date	Document Location	Acceptable [Y / N]	Initial / Date
Purchase Orders (4800000835/4800000836)	03.12.04			
URS (UR/UG/15)	17.07.2004			
Design Descriptions	---			
Engineering Drawings List	---			
Factory Acceptance Tests	---			
Commissioning / SAT Documentation	---			
Operation Manuals	---			
Authority Certificate	---			
Certificates of Conformity	---			
Mechanical Parts List	---			
Welder Qualifications	---			
Weld / Coupon Logs	---			
Boroscope Testing	---			
Pressure Test Certificate	---			
Maintenance Manuals	---			
Material Specifications	---			
Product contact material certificate	---			
Electrical Parts List	---			
Electrical Diagrams	---			
I / O Listing	---			
Electrical Installation test specification	---			
Instrument List	---			
Instrument calibration certificates	---			
Comments:				

Reviewed by		Date	

9.3 Equipment Verification

9.3.1 Objective

To verify that the equipment components are as specified.

9.3.2 Method

Visually examine all equipment components as listed in the tables below. Confirm that all specified requirements listed in SPECIFIED column [*Section 9.3.4. Data*] have been met. Record any deviations/non-conformances as described in *Section 11. Deviation Sheet*.

9.3.3 Acceptance Criteria

Equipment must be in conformance to specifications as listed in the SPECIFIED column in *Section 9.3.4 Data*.

9.3.4 Data

9.3.4.1 Purified Water Storage Tank

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no.	T-201			
Supplier	Pharmalab			
Quantity	1 No			
Capacity (Working)	3 m^3			
No. of Shadow Free, 360° Rotation Spray Ball	2 Nos.			
Electrically Tracked Vent Filter	Provided			
Vent Filter Rating	0.2 microns			
Thickness				
Shell	10 mm			
Top Dish	8 mm			
Bottom Dish	12 mm			
Jacket Shell	5 mm			
Jacket Bottom Dish	5 mm			
Cladding Shell	2 mm			
Cladding Bottom Dish	3 mm			
Limpet Coil	3 mm			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.3.4.1 Purified Water Storage Tank (cont'd)

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
M.O.C.				
Storage Tanks	SS 316 L			
Limpet Coil	SS 316 L			
Jacket	SS 316 L			
Cladding	SS 304			
Vent filter	PTFE			
Vent filter housing	SS 316 L			
Design Pressure				
Shell	3 / 3.75 / 5.6 Kg/cm^2 (Working / Design / Test)			
Jacket	3.5 / 4 / 6 Kg/cm^2 (Working / Design / Test)			
Limpet Coil	3.5 / 4 / 6 Kg/cm^2 (Working / Design / Test)			
Design Temperature				
Shell	(25 / 90) / 149 °C (Working / Design)			
Jacket	130 / 149 °C (Working / Design)			
Limpet Coil	130 / 149 °C (Working / Design)			
Supports	Ball feet arrangement			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.3.4.2 Sanitary Grade Centrifugal Pump

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no.	P-201			
Supplier	Grundfos			
Model Number	FM - 252			
Quantity	(1 No. Working + 1 No. Standby)			
Type	Sanitary Design, Centrifugal Tank			
Capacity	10 m^3/hr			
Head	96 - 122 meter			
Efficiency	88-89 %			
Motor (Rating / RPM)	4.0 KW / 2917 RPM			
MOC				
Casing	SS 316 L			
Impeller	SS 316 L			
Make				
Seal	Crompton			
Motor	Crompton			
VFD	Siemens			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.3.4.3 UV Sterilizer

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no.	UV-201			
Supplier	Alfa Purifire			
Model Number	AP 60			
Quantity	1 No.			
Flow Rate (Max/Min)	10 m^3/hr			
Bacteria Killing Capacity	99.9 %			
No. Of Arc Tubes	08			
Wave Length	254 mm			
UV Intensity	1.6 Milliwats / cm^2			
Alarms				
Low UV	Should be Provided			
Chamber Over Temperature	Should be Provided			
Lamp Failure	Should be Provided			
Over Temperature Power Supply Unit	Should be Provided			
MOC				
Tube	Quartz			
Body	SS-316 L			
Finishing				
Internal	Ra < 0.5 micro radian			
External	Ra < 0.8 micro radian			

Comments: **Spare UV intensity monitoring probe will be provided.**

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.3.4.4 Auto/Manual/Sample Valve

Check that all valves are identified and listed. Either attach the valve list as ANNEXURE or identify the location of the valve list. Verify all valves are tagged.

Supplier	Type	Part No	No. of Valves	Valve List [Attached or Refer Location]	Tags Available [Y/N]	Initial / Date
Crane	Diaphragm Valve	---	38			
Micro Pneumatic	Ball valve	---	3			
Crane	Sampling Valve	---	1			
Crane	Sampling Valve	---	3			
---	Gate Valve	---	7			
Fainger / Nirmal	Pressure Relief Valve	---	2			
---	Back Pressure Valve	---	1			
Avcon / Crane	Control Valve	---	5			
IMDC	3 way Control Valve	300 / 2005	1			
Crane + Avcon	3 way Control Valve	281 / 2005	2			

Comments:

Reviewed by		Date	

9.4. Instrumentation Verification

9.4.1 Objective

To verify the lists of instruments included in the system are as specified. (See *Section 9.5* for *Calibration Verification*)

9.4.2 Method

Visually check whether instruments are installed according to the engineering drawings and system specification. Confirm that all specified requirements have been met. List Tag number, serial number and location for each instrument. Record any deviations / non-conformances as described in *Section 11. Deviation Sheet*.

9.4.3 Acceptance Criteria

All instruments listed must be tagged and in conformance to the specifications listed in the SPECIFIED column in *Section 9.4.4. Data*.

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4 Data

9.4.4.1 Pressure Gauge

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	WAREE			
Type	Bourdon, Chemical Sealed Glycerline filled			
Quantity	2 No.			
Accuracy	± 1.0 % of fs			

	Location	Tag No.	Range (bar)
1	On Purified Water Storage Tank	PI 201	0 – 4
2	On Purified Water Return Line.	PI 202	0 – 10

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.1 Compound Pressure Gauge (cont'd)

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	WAREE			
Type	Compound Glycerine filled			
Quantity	1 No.			
Accuracy	± 1.0 % of fs			

	Location	Tag No.	Range (bar)
1	On Purified Water tank	CPI 201	0 -4

Comments:

Reviewed by		Date	

9.4.4.2 Pressure Transmitter

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	E & H			
Model	PMP 135 – A 2 GOIAIS			
Type	Diaphragm type, 4-20 mA, 2 Wire			
Quantity	3			
Accuracy	0.2 % of FSD			

S. No.	Location	Tag No./Serial No.	Range (bar)
1	On Steam Supply Line	PT 201	0 - 10
2	On Chilled Water Supply Line	PT 202	0 – 10
3	At Outlet of Pump	PT 203	0 – 10

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.3 Temperature Element

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	Radix			
Model	PT - 100			
Type	RTD			
Quantity	2			
Accuracy	± 0.3 at 0°C ± 0.8 at 100°C			

S. No.	Location	Tag No./Serial No.	Range (°C)
1	On Purified Water Storage Tank	TE 201	0 - 150
2	On Purified Water Return Line.	TE 202	0 - 150

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.4 Temperature Transmitter

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	Radix			
Model	TX 1 HM			
Type	Pt - 100			
Quantity	2			
Accuracy	99.9 %			

S. No.	Location	Tag No./Serial No.	Range (°C)
1	On Purified Water Storage Tank	TT 201	0 –150
2	On Purified Water Return Line.	TT 202	0 –150

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.5 Level Transmitter

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	E & H			
Model	FEC 12			
Type	RF Capacitance type, 4-20 mA, 2 Wire			
Quantity	1			
Range	0 – 3000 Liters			
Accuracy	<1 % of FSD			

S. No.	Location	Tag No./Serial No.	Range
1	On Purified Water Storage Tank	LT 201	0 – 3000 Liters

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.6 Flow Transmitter

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	E & H			
Model	40 E			
Type	Mass Flow type, 4-20 mA,			
Quantity	1			

S. No.	Location	Tag No.	Range (LPH)
1	On Purified Water Return Line.	FT 201	1000 - 11000

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.7 Conductivity Element (Probe)

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	Thronton			
Model	EP - 13			
Type	On – Line , Contacting			
Quantity	2			

S. No.	Location	Tag No.	Range (µs/cm)
1	On Purified Water Return Line.	CE 201	0 –10
2.	Before Pump Suction	CE 202	0 –10

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.4.4.8 Conductivity Transmitter

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	Thronton			
Model	Duel Channel			
Type	Indicating, 4-20 mA, 2 Wire			
Quantity	2			

S. No.	Location	Tag No.	Range (µs/cm)
1	On Purified Water Return Line.	CT 201	0 –10
2.	Before Pump Suction	CT 202	0 –10

Comments:

Reviewed by		Date	

9.5 Calibration Verification

9.5.1 Objective

To verify that critical instruments have been calibrated as specified.

9.5.2 Method

Verify that all critical instruments have been calibrated on site in accordance with the applicable vendor procedure and that current calibration certificates are available. Indicate the calibration certificate location, if a copy of the certificate is not attached. Record any deviation / non-conformance as described in *Section 11. Deviation Sheet*.

9.5.3 Acceptance Criteria

Critical instruments must be labeled and within the valid calibration period during qualification.

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.5.4 Data

Instrument	Tag No.	Cal'n Date	Maximum Calibration Interval	Calibration Due Date	Calibration Certificate Available [Y/N; Attached or Location]	Acceptable [Y/N]	Initial / Date
Conductivity Sensor	CE-201						
Conductivity Sensor	CE-202						
Conductivity Transmitter	CT-201						
Conductivity Transmitter	CT-202						
Flow Transmitter	FT-201						
Temperature Sensor	TE-201						
Temperature Sensor	TE-202						
Temperature Transmitter	TT-201						
Temperature Transmitter	TT-202						

Comments:

Reviewed by		Date	

9.6 Materials in Product Contact

9.6.1 Objective

To verify that all materials in product contact meet the specified requirements.

9.6.2 Method

Examine there is documented evidence that all materials that come into product contact meet the required specifications for material type and surface finish as applicable. Attach documents/identify the location. Utilities (such as nitrogen, air, steam, water) that subsequently come into contact with the pharmaceutical products shall be deemed as "product". Report any deviation / non-conformances as described in *Section 11. Deviation Sheet*.

9.6.3 Acceptance Criteria

All materials in product contact must be in conformance with the specifications listed in the SPECIFIED column in *Section 9.6.4. Data*.
Documented evidence attached/location checked.

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.6.4 Data

System Component	Reference Document [Title, No., Rev. No., Date]	Specified	Actual	Material Certificate Available [Y/N, Location]	Acceptable [Y/N]	Initial / Date
Storage tank	P&I Diagram for Storage and Distribution System, Dwg No. CWI108-01-01.	SS-316L				
Pump		SS-316L				
UV Housing		SS-316L				
Pipelines		SS-316L				
Valves & Fittings		SS-316L				
Instrument Wetted Parts		SS-316L				
O Rings		EPDM				
Gaskets		EPDM				
Diaphragm		EPDM				
Vent Filter		PTFE				

Comments:

Reviewed by		Date	

9.7 Services Verification

9.7.1 Objective

To verify that all services required for the operation of Purified Water Storage & Distribution System are available and connected to it and that these utilities conform to the system requirement.

9.7.2 Method

Visually examine that all services are available and connected in accordance with the applicable engineering drawings and system specifications. Complete the list of services installed in *Section 9.7.4 Data*. Record any deviation / non-conformances as described in *Section 11. Deviation Sheet*.

9.7.3 Acceptance Criteria

All services are available and connected in conformance to specifications listed in the SPECIFIED column in *Section 9.7.4 Data*.

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.7.4 Data

Services	Specified	Actual	Acceptable [Y/N]	Initial / Date
Compressed Air	• Pressure: 6 bar	• Pressure		
Steam	• Pressure: 3.1 Kg/cm^2 • Temperature: 130°C	• Pressure • Temperature		
Chilled Water	• Inlet Temperature: 7°C • Outlet Temperature: 12 - 15°C • Pressure: 2.5 Kg/cm^2	• Inlet Temperature • Outlet Temperature • Pressure		
Electricity	• Voltage: 415±10%V • Phases: 3 • Frequency: 50Hz±3%	• Voltage: • Phases: • Frequency:		

Comments:

Reviewed by		Date	

9.8 Automation and Control Systems Hardware Installation Verification

9.8.1 Objective

To verify that the control and monitoring devices are installed as specified.

9.8.2 Method

Visually examine the hardware components as listed in the SPECIFIED column in *Section 9.8.4. Data*. Report any deviation / non-conformances as described in *Section 11. Deviation Sheet*.

9.8.3 Acceptance Criteria

The hardware components must be in conformance to the specifications listed in the SPECIFIED column. Configuration / set point details must be documented for all configurable instruments.

9.8.4 Data

9.8.4.1 Controller (PLC)

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
CPU				
Manufacturer	Siemens			
Model	Simatic S7 – 300			
Firmware version /Serial No.	CPU 313 C – 2 DP			
Back up Battery	Siemens			
Power supply	24 V DC / 5 A			
Man Machine Interface				
Manufacturer	Siemens			
Model	TP 170 B			
Serial port RS-232C	RS 232			
Serial port RS-485C	RS 485			
Display	Mono			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.8.4.1 (cont'd)

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Analog/Digital Input/output cards				
Digital input				
Manufacturer	Siemens			
Model	D I 16			
No. of Channels	16			
Specification	DI 16 x DC 24 V			
Digital output				
Manufacturer	Siemens			
Model	DO 16			
No. of Channels	16			
Specification	DO 16 x DC 24 V			
Analog input				
Manufacturer	Siemens			
Model	SM 331			
No. of Channels	8			
Specification	AI 8 x 13 BIT			
Analog output				
Manufacturer	Siemens			
Model	SM 334			
No. of Channels	2			
Specification	AO 2 x 8 BIT			

Comments:

Reviewed by		Date	

9.9 Software Installation Verification

9.9.1 Objective

To verify that software installed is the specified version.

9.9.2 Method

Activate the system and check the software version number, date and location in the hard drive against the specifications listed in the SPECIFIED column in *Section 9.10.4. Data*. Check the availability and physical location of the software back-up copy against the specifications in the SPECIFIED column. Report any deviations / non-conformances as described in *Section 11. Deviation Sheet*.

9.9.3 Acceptance Criteria

The software installed has to be in conformance with the specifications listed in the SPECIFIED column.

9.9.4 Data

9.9.4.1 PLC Application

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Manufacturer	Siemens			
Version	TP V 5.3 + 5 PI			
Name of package	6 ES 7953 – 8 LF 11 – 0 AAO			
Location	Inside control panel			
Verification of back-up copy				
Availability [Y/N]	N			
Version	Siemens – TP			
Number	6 ES 7953 – 8 LF 11 – 0 AAO			
Man Machine Interface Programming Software				
Manufacturer	Siemens			
Version	TP 170 B			
Name of package	Protol			
Location	Front door of PLC			
Verification of back-up copy				
Availability [Y/N]	N			
Version	TP 170 B			

Comments:

Reviewed by		Date	

9.10 Control Systems Set-point and Software Parameter Verification

9.10.1 Objective

To verify the correct configuration of the critical software configuration parameters and set points

9.10.2 Method

For each critical control system component listed in the table provided, verify that the software configuration parameters and set points are as specified or record them as found. Document the results in the tables provided. For configurable instruments, attach either a copy of the configuration sheet as completed by the commissioning engineer on site, or (when applicable) a printout of the device set point values following commissioning. If neither a configuration sheet or set point value printout is available, record the actual configuration / set point values in Annexure 2 - 'Configuration Data'. Record any deviations / non-conformances as described in *Section 11 Deviation Sheet*.

9.10.3 Acceptance Criteria

The control system software component set points and configuration parameters are as specified in << Document Ref>>>. For configuration set points that are not specified before commissioning, actual configuration / set point values are recorded and attached as an Annex to this protocol

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9.10.4 Data

9.10.4.1 Control System Component Software Set point Verification

Control System Component	Specified	Actual	Acceptable [Y / N]	Initial / Date
LIAH 201	3000 Lts.			
LIAL 201	500 Lts.			
PIAL 203	02 Bar			
CIAH 201	1.1 µ Siemens			
CIAHH 201	1.3 µ Siemens			
FIARL 201	1000 LPH			
CIARH 202	1.1 µ Siemens			
CIARHH 202	1.3 µ Siemens			
TICL 202	0			
PIAL 201	3.1 Kg / cm^2			
PIAL 202	2.5 Kg / cm^2			
Manufacturer	Siemens			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

9.10.4.2 Operator Interface Terminal

Parameters	Specified	Actual	Acceptable (Y/N)	Initial / Date
Manufacturer	Siemens			
Location	On front door of control cabinet			
Identification Number	SC – T 4 F 83704			
Location of Configuration / Set Point Details	Set point screen			

Comments:

Reviewed by		Date	

9.11 Spare Parts List

9.11.1 Objective

To verify the availability of specified spare part lists

9.11.2 Method

Examine for the availability of spare part lists and attach either as *ANNEXURES* or indicate location of the actual spare part lists. Record any deviations / non-conformances as described in *Section 11 Deviation Sheet*.

9.11.3 Acceptance Criteria

Approved spare part lists must be available.

9.11.4 Data

Spare Parts List	Confirm Attached or Refer to Location	Initial / Date
General Spare Parts List		
Mechanical Spare Parts List		
Electrical Spare Parts List		
Instrument Spare Parts List		

Comments:

Reviewed by		Date	

9.12 Filter List

9.12.1 Objective

To verify all filters used in the system are as specified.

9.12.2 Method

Visually examine the filters used in the system are as listed in the SPECIFIED column in *Section 9.12.4. Data*. Relevant certificates and test reports must be available and attached as an *Annexure*. Confirm that all filters are installed in the correct orientation and that all specified requirements have been met. Record any deviations / non-conformances as described in *Section 11. Deviation Sheet*.

9.12.3 Acceptance Criteria

Filters must be in conformance with specifications listed in the SPECIFIED column.

9.12.4 Data – Vent Filter

Parameters		Specified	Actual	Acceptable (Y/N)	Initial / Date
Description		Vent Filter			
Model /Part No	Housing	Micro Filt			
	Element	Cuno			
Type		Electrically traced, hydrophobic filter			
No of filters		1 No.			
Location		Mounted on Purified Water Storage Tank			
Material	Housing	SS 316 L			
	Element	PTFE			
Tag Number		VF 201			

Comments:

Reviewed by		Date	

9.13 Visual Inspection

9.13.1 Objective

To verify that the Purified Water Storage & Distribution System is ready for operation.

9.13.2 Method

Visually examine that the installation of Purified Water Storage & Distribution System is completed and that all instrument / component packaging is removed. Visually examine the cleanliness of the Purified Water Distribution System and verify that all connections to instrument/components (electrical wire, hoses, pipes, clamps, etc) are firmly affixed. Confirm that the Purified Water Distribution System is ready for operation.

9.13.3 Acceptance Criteria

The specifications listed in the SPECIFIED column are met.

9.13.4 Data

S. No.	SPECIFIED	Acceptable [Y/N]	Initial / Date
1.	Installation of Purified Water Storage & Distribution is completed.		
2.	Purified Water Storage & Distribution System is clean.		
3.	All instrument/component packaging is removed.		
4.	All instrument/ component hoses, piping, clamps, wire etc firmly affixed.		
5.	All accessories are available.		

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

10. CHECKLIST OF ALL TESTS AND CHECKS

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

Reference No.	Tests or Checks	Executed [Y/N]	Comment
9.1	Drawing Verification		
9.2	Documentation Verification		
9.3	Equipment Verification		
9.4	Instrumentation Verification		
9.5	Calibration Verification		
9.6	Materials in Product Contact		
9.7	Services Verification		
9.8	Automation and Control System Hardware Installation Verification		
9.9	Software Installation Verification		
9.10	Control systems set-point and software parameter verification		
9.11	Spare Parts List		
9.12	Filter List		
9.13	Visual Inspection		

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

11. DEVIATION 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 IQ File.

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Exception / Deviation No.	Exception / Deviation Title	Status

Comments:

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.
- SOP No BQA)-017-"Handling of Deviations".
- SOP No BQA)-011-"Change Control Procedure".

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13. LIST OF ANNEXURES

Annexure No.	Document Title

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

14. SUMMARY

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM

15. APPROVALS

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

EXECUTED BY:

Organization	Name	Designation	Signature	Date

REVIEWED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER DISTRIBUTION SYSTEM