



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

**INSTALLATION QUALIFICATION
PROTOCOL
FOR
PROCESS WATER GENERATION &
DISTRIBUTION SYSTEM**



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

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 PROCESS WATER

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

1. OBJECTIVE

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

- To verify that the Process Water Generation & 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 Process Water Generation & Distribution System serving the Scope incorporates qualification of all components starting from Chlorination System, Raw Water Storage & Pumping System, Dual Media Filter, Potable Water Storage & Pumping System, De-chlorination System, Serial Softeners with Brine Measuring Tank & Salt Saturation Tank, Soft Water Storage & Pumping System and Process Water Generation & Pumping System.

This protocol will define the methods and documentation used to qualify the Process Water Generation & Distribution System for IQ. Successful completion of this protocol will verify that the Process Water Generation & Distribution System meets all acceptance criteria and is ready for Operational Qualification.

3. RESPONSIBILITIES

All work is to be performed underoversight and according toapproved procedures.

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 currentpolicies 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.



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- Regulatory Compliance Review of the completed IQ Protocol
- Review and Approval of the executed IQ Protocol.

4. SYSTEM DESCRIPTIONS

The purpose of Process Water Generation & Distribution System is to generate potable water & process water for Potable water distribution system for Formulation & Process Area B, Process water distribution system and feed for Purified water generation system. The Process Water Generation & Distribution comprises of Chlorination System, Raw Water Storage & Pumping System, Dual Media Filter, Potable Water Storage & Pumping System, De-chlorination System, and Serial Softners with Brine Measuring Tank & Salt Saturation Tank, Soft Water Storage & Pumping System and Process Water Storage & Pumping System.

Raw Water from Deep bore-well (2 nos.) is taken as a feed for this system. On line chlorination is done through NaOCl dosing. Chlorinated water is stored in Raw Water storage tanks. Chlorination is carried out for water before being stored in Tank to protect water from bacterial growth. Raw Water from water storage tanks are pumped by Raw Water transfer pump (1W+1S) to 1 No. Multi-grade filter. Filtered water coming from Multi-grade filter is stored in 3 Nos. potable water storage tank. Potable Water from Potable Water storage tank is pumped by potable water pumps (1W+1S) to 2 Nos. of softners. Online Na₂S₂O₅ (Sodium Meta Bi-Sulphite) dosing is done on Potable Water coming from water transfer pump to remove dissolved chlorine in water. De-chlorination is carried out for water entering to softners for protection of resin against residual chlorine. Tapping for supply to Potable Water Distribution System (Hydro Pneumatic System) for Formulation Plant is done before De-chlorination.

Water coming from softner is stored in 2 Nos. soft water tank Soft Water from one tank is pumped by soft water transfer pump (1W+1S) to feed as make up water for Cooling Tower HVAC, make up water for Cooling Tower DG sets, make up water for Hot Water HVAC, make up water for Chilled Water HVAC & make up water Boiler.

Soft Water from second soft water storage tank is pumped through process water transfer pumps (1W+1S) to feed for Purified Water Generation and to Process Water Distribution. Online chlorination is done after transfer pump (P804 A/B).

Process Water Generation and Distribution System is being supervised and controlled by Panel mounted microprocessor stand alone indicator & controllers alarm with annunciation.

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.



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

When appropriate, Drawings shall be marked up according *to as following*

- 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 bybefore the change request is closed out.



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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]	Initial / Date
FAT					
Commissioning / SAT					

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9. TESTS AND CHECKS

The following tests and checks are to be completed for IQ of Process Water Generation & 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.



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9.1.4 Data

Reference Engineering Drawings [Title, No., Originator (Company)]	Drawings Rev. No. & Issue Date	Document Location	Acceptable [Y/N]	Initial / Date
P&I Diagram for Water System				
P&I Diagram for Process Water System				
Equipment Layout ION Exchange (India) Pvt. Ltd.				
Foundation Details for Filtered Water Tank – ION Exchange (India) Pvt. Ltd.				
Foundation Details for Soft Water Tank ION Exchange (India) Pvt. Ltd.				
GA Foundation & Tech. Details For 2200 Dia Softner (2 Sheets) ION Exchange (India) Pvt. Ltd.				
GA Foundation & Tech. Details For 1600 Dia. Multigrade Filter ION Exchange (India) Pvt. Ltd.				
Flow Diagram ION Exchange (India) Pvt. Ltd.				
GA Drawing for Pump				
GA Drawing for Pump				
GA Drawing for Pump				
GA Drawing for Pump				
Instrument wiring diagram for Local Inst. Control Panel				

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

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 Process Water Generation & 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 forSOP's 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 perprocedure.



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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		√				
Certificates of Conformity		√				
Spare Parts List		√				
Mechanical Documentation						
Mechanical Parts List		√				
Description of mechanical parts		√				
Pressure Test Certificate		√				
Maintenance Manuals		√				
Material Specifications		√				
Product contact material certificate		√				
Electrical Documentation						
Electrical Parts List		√				
Electrical Diagrams / Relay diagram		√				
Instrument List		√				
Instrument calibration certificates		√				



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.2.4.1 Document Details

Document Title / No./ Originator (Company)	Revision No. / Issue Date	Document Location	Acceptable [Y / N]	Initial / Date
Purchase Orders				
URS (UR/UG/29)				
Design Descriptions				
Engineering Drawings List				
Factory Acceptance Tests				
Commissioning / SAT Documentation				
Operation Manuals				
List of control parameters and set points				
Mechanical Parts List				
Maintenance Manuals				
Material Specifications				
Electrical Parts List				
Electrical Diagrams				
Instrument List				
Instrument calibration certificates				

Comments:

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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*.



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9.3.4 Data

9.3.4.1 Online Chlorination System (.....) and (.....)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No			
Supplier	ION Exchange			
Model Number	D-91			
Quantity	1			
Dosing Chemical	NaOCl			
Flow Rate	40 m ³ /hr			
Dosage	0.2 ppm			
Concentration of Solution	20 %			
Dosing Method	Proportional Dosing			
Chlorine Content (Residual)	0.2 ppm			
NaOCl Preparation Tank				
Capacity	0.2 m ³			
Diameter	0.6 meter			
Height	0.96 meter			
MOC	HDPE			
Dosing Pumps				
Quantity	2 (1W+1S)			
Type	Electronic Metering			
Capacity	16.7 lph			
Max. Pressure Developed	9 Kg/cm ²			
Power Absorbed	0.06 Kw			
MOC of Pump	PP			
Make of Pump	Milton Roy / Prominent			

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.2 Multi Grade Filter

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag No./Serial No			
Manufacturer	ION Exchange			
Quantity	1			
Flow Rate	60 m ³ /Hr			
Type of Filter	Multi-grade Sand Filter			
Diameter x Height	1600 x 2500 mm			
Material Of Construction	MS			
Surface Flow Rate	30 m ³ /hr/m ²			
Thickness of Shell	8 mm			
Corrosion Allowance	1.5 mm			
Pressure At Inlet Of Filter	4.7 Kg/cm ² (g)			
Pressure At Outlet Of Filter	4.2 Kg/cm ² (g)			
Pressure Drop Across The Filter	0.8 (Max) Kg/cm ²			
Back Wash Details				
Flow Rate	80 m ³ /hr			
Pressure Drop After Backwash	0.2 Kg/cm ²			
Duration Of Backwash	20-25 minute			
Quantity Of Back Wash Effluent	28 – 30 m ³			
Source Of Back Wash	RAW WATER			
Design Output For Filter Per Day	960 (Approx) m ³ /day			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.3 Potable Water Storage Tank (.....A/B/C)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag No./Serial No.	T-801 A/B/C			
Manufacturer	Sintex			
Quantity	3			
Capacity	20 m ³ (each)			
Thickness of shell	12 mm			
MOC	HDPE			

Comments:

Reviewed by

Date



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9.3.4.4 Serial Softners (.....)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag No./Serial No	(X-804)			
Manufacturer	ION Exchange			
Quantity	2			
Type of Softener	CO- FLOW			
Flow Rate	55 m ³ /hr			
Operation Time	16 hours			
Regeneration Time	2 hours			
Size Of Softner (Dia X Height)	2200 x 2500 mm			
Moc of Shell	MS			
Thickness of Shell / Dished End	8 / 10 mm			
Corossion Allowance	1.5 mm			
Resin Details				
Resin Type	225 Na (Food Grade)			
Resin Quantity	5500 lts. / SOFTNER			
Resin Life	4-5 years			
Exchange Capacity Resin Grade	63.5 Kgs/m ³			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.4 Serial Softners (.....) cont...

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Operation Mode	MANUAL			
Regeneration Mode	MANUAL			
Pressure At Inlet Of Softener	4.5 Kg/cm ² (g)			
Pressure At Outlet Of Softener	4 Kg/cm ² (g)			
Pressure Drop Across The Softener	0.8 Kg/cm ² (max)			
Slow Rinse				
Type Of Water For Slow Rinse	FILTERED WATER			
Fast Rinse				
Type Of Water For Fast Rinse	Filtered Water			
Fast Rinse Flow Rate	55 m ³ /hr			
Brine Measuring Tank				
Quantity Required Per Regeneration	880 Kg			
Regeneration Method	By Ejector			
Frequency Of Regeneration	After 16 hr			
Hardness Of Water At Outlet Of Softner	< 5 ppm (Commercial Zero)			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.5 Brine Measuring Tank

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	ION Exchange			
Quantity	2 (1 FOR EACH SOFTNER)			
MOC	MS			
Capacity	3.4 m ³			
Size (Dia X Height)	2200 x 900 mm			

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.6 Salt Saturation Tank

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	ION Exchange			
Quantity	1			
MOC	RCC			
Size (Length x Width x Depth)	3000 x 1500 x 1600			

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.7 Online De-Chlorination System

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No			
Supplier	ION Exchange			
Quantity	1			
Dosing Chemical	Sodium meta bisulphate			
Dosage	4-5 ppm			
Dosing Method	Proportional Dosing			
Chlorine Content (Residual)	0.2 ppm			
NaOCl Preparation Tank				
Capacity	1 m ³			
MOC	HDPE			
Dosing Pumps				
Quantity	2 (1W+1S)			
Type	Electronic Metering / Manual			
Capacity	15 lph			
Power Absorbed	0.06 Kw			
MOC of Pump	PP			
Make of Pump	Milton Roy / Prominent			

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.8 Soft Water Storage Tank

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag No./Serial No	T-802 A/B			
Manufacturer	Sintex			
Quantity	2			
Capacity	20 m ³ (each)			
MOC	HDPE			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.9 Equipment under scope of Enmax Systems (Grundfoss)

9.3.4.9.1 Raw Water Transfer Pump

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No	P-800 A/B			
Manufacturer	Grundfoss			
Model No:	A 96548580 P 20508			
Type	CR 64-2			
Rated Capacity	60 m ³ /hr			
MOC Impeller	SS 304			
MOC Casing	SS 304			
Type of packing	Mechanical Seal			
Power absorbed / motor rating	9.7 / 11 KW			
Rated Efficiency	77 %			
Shut of Head	54 Meter			
Minimum Continuous Flow	34.5 m ³ /hr			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.9.2 Potable Water Transfer Pump (P 801 A/B)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No.	P-801 A/B			
Manufacturer	Grundfoss			
Type	CR 64-2			
Rated Capacity	55 m ³ /hr			
MOC Impeller	SS 304			
MOC Casing	SS 304			
Type of packing	Mechanical Seal			
Power absorbed / motor rating	9.37 / 11 KW			
Rated Efficiency	76.3 %			
Shut of Head	54 meter			
Minimum Continuous Flow	34.5 m ³ /hr			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.9.3 Soft Water Transfer Pump (P-803 A/B)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No	P-803 A/B			
Manufacturer	Grundfoss			
Type	CR 32-2-2			
Rated Capacity	25 m ³ /hr			
Head	27 meter			
MOC Impeller	SS 304			
MOC Casing	SS 304			
Type of packing	Mechanical Seal			
Power absorbed / motor rating	2.46 / 3 KW			
Rated Efficiency	73.4 %			
Shut of Head	30 meter			
N.P.S.H (R)	1.42 meter			

Comments:

Reviewed by		Date	
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9.3.4.9.4 Process Water Transfer Pump

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No	P-804 A/B			
Manufacturer	Grundfoss			
Model No:	A 96500970 P 010442			
Type	CRN 10-8			
Rated Capacity	10 m ³ /hr			
Head	81 meter			
MOC Impeller	SS 304			
MOC Casing	SS 304			
Type of packing	Mechanical Seal			
Power absorbed / motor rating	2.58 / 3 KW			
Rated Efficiency	85 %			
Shut of Head	80 meter			
Minimum Continuous Flow	5.5 m ³ /hr			
N.P.S.H (R)	2.1 meter			

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.9.5 Process Water Transfer Pump (P-1401 A/B)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag no./Serial No.	P-1401 A/B			
Manufacturer	Grundfoss			
Model No:	CRN 15-4			
Rated Capacity	16.5 m ³ /hr			
Head	44.8 meter			
MOC Impeller	SS 304			
MOC Casing	SS 304			
Type of packing	Mechanical Seal			
Power absorbed / motor rating	2.88 / 4 KW			
Rated Efficiency	71.3 %			
Shut of Head	53 meter			
Minimum Continuous Flow	8.36 m ³ /hr			
N.P.S.H (R)	1.36 meter			

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.10 Equipment under scope of AIPA Automation Pvt. Ltd.

9.3.4.10.1 Local Instrument Control Panel (LCP-01)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag No./Serial No	LCP-01			
Supplier	AIPA Automation Pvt. Ltd.			
Quantity	1			
Type	Weather proof			
Thickness	3 mm			
MOC	ALCOSY			
Panel Mounting Instrument	Flush Mounting			
Make Relay	PLA			
Electric Power supply for Panel	230 V AC			
SMPS Power supply for Panel Instrument	24 V DC, 5Amp.			

Comments:

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.3.4.11 Equipment under scope of

9.3.4.11.1 Raw Water Storage Tank

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Tag No./Serial No.	T – 800 CID			
Supplier			
Quantity	4			
Capacity	100 m ³ (each)			
MOC	RCC			

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

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 PROCESS WATER

9.4.4 Data

9.4.4.1 Instruments under scope of ION Exchange (India) Pvt. Ltd.

9.4.4.1.1 Pressure Gauge

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	FGB			
Type	Bourdon			
Quantity	6			
Accuracy	± 1 % FSD			

S. No.	Location	Range (Kg/cm ²)	Tag No./Serial No
1	Inlet nozzle of Dual Media Filter	0 - 7	C 49663
2	Outlet nozzle of Dual Media Filter	0 - 7	C 49776
3	Inlet nozzle of Softner 1	0 - 7	C 47582
4	Outlet nozzle of Softner 1	0 - 7	C 49699
5	Inlet nozzle of Softner 2	0 - 7	C 47726
6	Outlet nozzle of Softner 2	0 - 7	C 47539

Comments:

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Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2 Instruments under the scope of

9.4.4.2.1 Pressure Gauge

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	Wavee			
Model	KI : 1,0			
Type	Bourdon			
Quantity	10			
Accuracy	± 1 % FSD			

S. No.	Location	Tag No./Serial No	Range
1	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
2	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
3	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
4	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
5	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
6	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
7	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
8	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
9	At outlet of Pump Tag		0 – 10.5 Kg / cm ²
10	At outlet of Pump Tag		0 – 10.5 Kg / cm ²

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.2 Level Switch

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	Pune Techtrol (P) Ltd.			
Type	Internal Displacer Type			
Quantity	5			

S. No.	Location	Tag No.
1	Tank T 800 C	LS 801
2	Tank T 800 D	LS 802
3	Tank T-802 A	LS 808
4	Tank T-802 B	LS 810
5	Tank T-1401	LS 1401

Comments:

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Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.3 Level Transmitter

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	AIPA Automation Ltd			
Model	ABB			
Type	DP Transmitter, 4-20 mA, 2 Wire			
Quantity	1			
Range	0 – 2000 mmWC			
Accuracy	± 0.1 % FSD			

S. No.	Location	Tag No.	Range
1	For Tank T 801 A/B/C	LT 806	

Comments:

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PHARMA DEVILS

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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.4 Level Indicator (Panel Mounted)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	AIPA Automation Ltd			
Model	ABB			
Type	Microprocessor Flush Mounted			
Quantity	1			
Range	0 – 1000 mmWC (0 – 100 %)			

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.5 Flow Element (Orifice)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	AIPA Automation Ltd.			
Type	Orifice with Flange pressure tapings			
Quantity	6			

S. No.	Location	Tag No.	Range (mm WC)
1	Line POW-811-100-C1A	FE 802	0 - 500
2	Line PRW-815-40-B1A	FE 803	0 - 2000
3	Line SW-815-50-C1A	FE 807	0 - 2000
4	Line SW-801-100-C1A	FE 808	0 - 2000
5	Line SW-817-40-C1A	FE 810	0 - 2000
6	Line RW-803-100-C1A	FE 812	0 - 2000

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.6 Flow Transmitter

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	AIPA Automation Ltd.			
Model	ABB			
Type	DP Transmitter, 4-20 mA, 2 Wire			
Quantity	6			
Accuracy	0.1 % FSD			

S. No.	Location	Tag No.	Range (mm WC)
1	Line POW-811-100-C1A	FT 802	0 - 500
2	Line PRW-815-40-B1A	FT 803	0 - 2000
3	Line SW-815-50-C1A	FT 807	0 - 2000
4	Line SW-801-100-C1A	FT 808	0 - 2000
5	Line SW-817-40-C1A	FT 810	0 - 2000
6	Line RW-803-100-C1A	FT 812	0 - 2000

Comments:

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Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.7 Integral Orifice Flow Transmitter

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	AIPA Automation Ltd.			
Model	ABB			
Type	DP Transmitter, 4-20 mA, 2 Wire with integral Orifice			
Quantity	1			
Accuracy	0.1 % FSD			

S. No.	Location	Tag No.	Range (mm WC)
1	Line SW-301-25-C1A	FE/FT 806	0 - 2000

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.8 Flow Indicator / Integrator (Panel Mounted)

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	AIPA Automation Ltd.			
Model	ABB			
Type	Microprocessor Flush Mounted			
Quantity	5			

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.4.4.2.9 Chlorine Analyzer

Parameter	Specified	Actual	Acceptable (Y/N)	Initial / Date
Supplier	E&H			
Model	9027.90			
Type	Amperometric type with Gold Cathode / Silver Anode with Auto temp. Compensation			
Quantity	1			
Accuracy	± 1 %			
Associating Parts	1. Trace Cl Measuring Cell			
	2. Flow Fit			
	3. Measuring Cable			
	4. Liquisis			
	5. pH Electrode			
	6. Junction Box			
	7. pH Measuring Cable			

S. No.	Location	Tag No.	Range
1	Line RW-803-100-C1A	Cl ₂ A 801	0 – 5 mg/l

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

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.

9.5.4 Data

9.5.4.1 Instrument under scope of Ion Exchange (India) Pvt. Ltd.

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
Pressure Gauge	C 49663						
Pressure Gauge	C 49776						
Pressure Gauge	C 47582						
Pressure Gauge	C 49699						
Pressure Gauge	C 47726						
Pressure Gauge	C 47539						

Comments:

Reviewed by

Date



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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.5.4.2 Instrument under scope of

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
Pressure Gauge	P-802 A						
Pressure Gauge	P-802 B						
Pressure Gauge	P-803 A						
Pressure Gauge	P-803 B						
Pressure Gauge	P-804 A						
Pressure Gauge	P-804 B						
Pressure Gauge	P-805 A						
Pressure Gauge	P-805 B						
Pressure Gauge	P-1401A						
Pressure Gauge	P-1401B						
Level Transmitter	LT-806						
Level Indicator	LI 806						
Flow Transmitter	FT-802						
Flow Transmitter	FT-803						
Flow Transmitter	FT-807						
Flow Transmitter	FT-808						
Flow Transmitter	FT-810						
Flow Transmitter	FT-812						

Comments:

Reviewed by

Date



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.6 Services Verification

9.6.1 Objective

To verify that all services required for the operation of the system are available and connected to the system and that these utilities conform to the system requirement.

9.6.2 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 9.6.4 Data*. Record any deviation / non-conformances as described in *Section 11. Deviation Sheet*.

9.6.3 Acceptance Criteria

All services are available and connected in conformance to specifications listed in the SPECIFIED column in *Section 9.6.4 Data*.

9.6.4 Data

Services	Specified	Actual	Acceptable [Y/N]	Initial / Date
Compressed Air	Pressure 6 Kg/cm ²	Pressure :		
Electricity	<ul style="list-style-type: none">• Voltage: 415±10% V• Phases: 3• Frequency: 50Hz±3%	<ul style="list-style-type: none">• Voltage:• Phases:• Frequency:		

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.7 Spare Parts List

9.7.1 Objective

To verify the availability of specified spare part lists

9.7.2 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*.

9.7.3 Acceptance Criteria

Approved spare part lists must be available.

9.7.4 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	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

9.8 Visual Inspection

9.8.1 Objective

To verify that the Process Water Generation & Distribution System is ready for operation.

9.8.2 Method

Visually examine that the installation of Process Water Generation & 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.

9.8.3 Acceptance Criteria

The specifications listed in the SPECIFIED column are met.

9.8.4 Data

S. No.	Specified	Acceptable [Y/N]	Initial / Date
1.	Installation of Process Water Generation & Distribution is completed.		
2.	Process Water Generation & 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 PROCESS WATER

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	Services Verification		
9.7	Spare Parts List		
9.8	Visual Inspection		

Comments:

Reviewed by		Date	
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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

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 “Handling of Deviations”.
- SOP “Change Control Procedure”.



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INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER



INSTALLATION QUALIFICATION PROTOCOL FOR PROCESS WATER

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