INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION 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
Jacobs Engineering		Validation Engineer		

CHECKED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

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INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

1. OBJECTIVE

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

- To verify that the Purified Water Generation 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 Generation System serving the …….. Scope incorporates qualification of all Purified Water Generation components from Feed water inlet, upstream of Sample valve SV1, up to and including Product three way diverter valve V44 in the water treatment stream and oil free filtered Instrument air downstream of V32

This protocol will define the methods and documentation used to qualify the Purified Water Generation System for IQ. Successful completion of this protocol will verify that the Purified Water Generation 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.

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

The Purified water generation system is fed by Chlorinated soft water complying with IS Standards as filtered through 5.0 µ cartridge filter to control SDI. The quantity of the free chlorine in Feed water shall be kept within 0.02 ppm by SMBS dosing before entering to Purified Water Generation Skid. The Purified Water Generation System shall produce Purified water in compliance with current USP 28, at flow rate of 4 m^3/hour and pressure of < 1.5 bar. Pre conditioning skid consists of heat exchanger, SMBS dosing and NaOH dosing which controls temperature, Conductivity and pH of water respectively. Feed to the purified water system shall be at 7.0 bars from the pre conditioning skid. Pre conditioning skid consists of heat exchanger, SMBS dosing and NaOH dosing which control temperature, chlorine and pH of water respectively. The system comprises of pre-treatment and final treatment section. The pre-treatment section of Generation skid consists of Two Base Exchange Softeners, to reduce total hardness in feed water, and a 5.0 µ cartridge filter to reduce particulate loading on final treatment section. The pre treated feed water is fed to storage to in feed water tank TK1. The pre-treatment section is followed by Reverse Osmosis and Continuous De-Ionization process to generate required grade Purified water. The treated water, which meets the quality requirements specified, enters as Purified Water into the Purified Water storage tank and distributed to manufacturing premises through Distribution skid.

Qualification activities for the PW Generation System incorporate the following system components as listed below in order of process:

- **Two Base Exchange Softeners**: BES-1 and BES-2. The Softener is used to reduce total hardness in feed water
- **5.0 µm cartridge filter FLT 1**: This cartridge filter is used to reduce particulate loading on final treatment section
- **Chlorine Monitor**: Free chlorine will be monitored by chlorine monitor before entrance to the

Purified Water generation skid by taking sample at frequency to be determined in Phase 1 & 2 trials and will be a part of operating SOP.

- **Feed water Tank TK1**: Filtered water from the 5.0 µm cartridge filter is stored in this Tank. The Feed water Tank is of 100 Litre capacity and provided with a electric heater. This tank serves as a multipurpose break tank, heating chamber for hot water sanitisation, CIP tank for final treatment section and an expansion tank during hot water sanitisation
- **RO feed pump PU 1**: This pump is variable speed driven and feeds RO unit. This pump's speed is set by PLC to achieve pre-set flow and pressure.
- **RO Unit R01**. This is a two-pass arrangement comprising high pressure Stainless Steel vessels fitted with hot water sanitisable RO elements. The RO feed pump force feeds the feed water to RO unit; the RO unit is designed to have recovery rate of 75%, producing permeate at $4m^3$/hour.
- **Degasser DEG A/B**: Degasser enhances the performance of downstream Continuous De-ionization units. Degasser module(s) contain thousands of fine Hydrophobic hollow tubes that will allow only the gases and not the water to pass through. A stream of oil free filtered Instrument air is used to strip out excess levels of Carbon-di-oxide from RO permeate
- **CDI-LX Units CDI-LX A/B**: Process water leaving the RO unit is passed to the CDI System which consists of alternating cation and anion exchange modules. High voltage Direct Current is applied to the electrodes located at either end of the CDI modules, this action will remove ions from the feed water and regenerate ion resins inside the modules continuously. The module produces consistent, predictable water quality which is better than 95% removal with a feed water conductivity of 50 µ S/cm
- **Saturator for regenerating Softeners with brine solution**. A multi port valve located on each softener controls the regeneration process. Softeners are interlocked so that only one can be regenerated at a time.
- **CIP systems (chemical):** As the chemical cleaning requirements of various parts of final treatment are different, they can be isolated for chemical cleaning in place as three different circuit namely CIP1 (low pressure chemical cleaning of RO unit) and CIP 2 (high pressure cleaning of RO unit) by isolating RO unit from Degasser and CDI; CIP 3 is for CDI-LX Units cleaning. They are all semi-automatic process selected and prompted by PLC.
- **Control System**. The PW Generation System is controlled and monitored via a Siemens S7-300 PLC (Programmable Logic Controller) and Human Machine Interface (HMI), with an external PLC

Interface to DCS/SCADA using Modbus Protocol and status control system

- **Alarms and Safety Interlocks.** Three different alarm types are incorporated namely warning, non-critical alarm and critical alarms. Emergency stop is hardwired independently from the control system and can thus override control of the PLC.
- **Hot water sanitization:** Final treatment section including the feed water tank is hot water sanitisable up to 85 ° C on automatic control set via HMI. It can be either manually initiated or run automatically at a pre-set day and time via time clock.

5. DOCUMENTATION REQUIREMENTS

The IQ File should include:

- Installation Qualification 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 ..... procedure.* Specifically, the following instructions apply:

- 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 *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 ……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.

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	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9. TESTS AND CHECKS

The following tests and checks are to be completed for IQ of Purified Water Generation 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 and filed correctly. Drawings must conform to …… General Drawing Standards. Where relevant, documents must be approved as …….procedure.

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 ORION 4000.				
Outline & Connection Detail ORION 4000.				
Equipment Layout				

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 system 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 Certifications			√			
Certificates of Conformity		√				
Spare Parts List		√				
Mechanical Documentation						
Mechanical Parts List		√				
Welder Qualifications		√				
Weld / Coupon Logs		√				
Boroscope Testing		√				
Hydraulic Diagrams	√					
Maintenance Manuals		√				
Material Specifications		√				
Product contact material certificate		√				
Electrical Documentation						
Electrical Parts List		√				
Electrical Diagrams		√				
I/O Listing		√				
Instrument List		√				
Instrument calibration certificates		√				

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.2.4.1 Document Details

Document Title	Doc. No./ Originator	Revision No. / Issue Date	Document Location	Acceptable [Y / N]	Initial / Date
Purchase Orders	4800000862	---			
URS	UR/UG/15	---			
Design Descriptions	---	---			
Engineering Drawings List	---	---			
Factory Acceptance Tests	S51_Orion_Std / Rev10	----			
Commissioning / SAT Documentation	---	---			
Operation Manuals	---	---			
Certificates of Conformity	CE0469A ORION V5 vol 1 of 1	---			
Mechanical Documentation					
Mechanical Parts List	---	---			
Welder Qualifications	---	---			
Weld / Coupon Logs	---	---			
Boroscope Testing	---	---			
Maintenance Manuals	---	---			
Material Specifications	---	---			
Product contact material certificate	---	---			
Electrical Documentation					
Electrical Parts List	---	---			
Electrical Diagrams	---	---			
I/O Listing	---	---			
Description of electrical parts	---	---			
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 Heat Exchanger with Dosing System

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Make	Alfa			
S. No.	30108-73-303			
Working Temperature	60°C (Max.)			
Resign Pressure	5.1 ATG			
Plate Pack Length	48 mm			
MOC	SS 316			
Dosing Pump				
Make	Milton Roy			
Capacity	17 Lt / Hr			
Model	0-92			
S. No.	1764			
Pressure	7 Kg (Max.)			
Quantity	02			

9.3.4.2 Base Exchange Softener

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Softener -1				
Tag no./Serial No	C/BES 1			
Supplier	VWS			
Model/Part no.	EW03 3497257			
Softener -2				
Tag no./Serial No	C/BES 2			
Supplier	VWS			
Model/Part no.	EW03 3527514			

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9.3.4.3 RO/CDI-LX Feed water Tank (Multi Purpose Break Tank)

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Tag No./Serial No	TK 1			
Supplier	F&G Stainless Steel			
Tank capacity	100 L			
Spray ball Tag No/ Supplier/size/part no:	S-Ball/HPE/63 mm dia./SB 1B/			
Tanks vent Strainer Tag No. / Supplier/ part no	STR 1/ DPL/ DP K77320 08G			
Immersion heater Tag No/ capacity/supplier/ part no:	HT 1/18 KW/ HEATEX/HR F6-18SA			

9.3.4.4 HP RO Feed pump

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Tag No./Serial No	PU 1			
Supplier	GRUNDFOS			
Model/Part No	CRN16-160			
Nominal rating	16 m^3 / hr			
Motor HP (KW)	15			
Volt/Phase	440V±10%/3Phase			

9.3.4.5 RO Module

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
RO Module-1				
Tag no. / Serial No	RO1			
Housing Manufacturer	SOMMER + STRASSBURGER			
Housing Model / Part No:	P8072 223 602345-07-01			
Membrane Manufacturer	DOW FILMTEC			
Membrane Part No:	HSRO-390-FF			
RO Module 2				
Tag no. / Serial No	RO 2			
Housing Manufacturer	SOMMER + STRASSBURGER			
Housing Model / Part No:	P8072 213 602345-07-01			
Membrane Manufacturer	DOW FILMTEC			
Membrane Part No:	HSRO-390-FF			

9.3.4.6 Degasser

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Degasser A				
Tag No./Serial No	DEGAS 1			
Supplier	CELGARD			
Model/Part No	4X28 X50 SS Contactor (G504)			
Type	Hollow fibre Degasser 4"x28"			
Degasser B				
Tag No./Serial No	DEGAS 2			
Supplier	CELGARD			
Model/Part No	4X28 X50 SS Contactor (G504)			
Type	Hollow fibre Degasser 4"x28"			

9.3.4.7 Continuous De-ionization Module

Parameter	Specified	Actual	Acceptable	Initial /

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			[Y / N]	Date
Module –A				
Tag No./Serial No	CDI-LX A			
Supplier	VWS US FILTER			
Model/Part No	IP-LX M24H			
Nominal rating	12.5 GPM			
No. of Plates	24			
Module B				
Tag No./Serial No	CDI-LX B			
Supplier	Ion Pure Technofiers			
Model/Part No	IP-LX M24H			
Nominal rating	12.5 GPM			
No. of Plates	24			

Comments:

Reviewed by		Date	

9.3.4.8 Auto/Manual/sample Valve

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

Supplier	Type	VWS Part No	No. of Valves	Valve List [Attached or Refer Location]	Tags Available [Y/N]	Initial / Date
VWS GEMU	Manual diaphragm	726778	8			
VWS GEMU	Manual diaphragm	538797	1			
VWS GEMU	Manual diaphragm	726776	4			
VWS GEMU	Manual diaphragm	VALV22351	3			
VWS GEMU	Aseptic Manual diaphragm	726779	1			
BWT	Ball Sanitary	726767	1			
USF/ITT	Manual Sanitary	726759	6			
TECHNIQUIP	Manual Needle regulated	726572	2			
DPL	3-way Auto Plug	726788	1			
VWS GEMU	Auto diaphragm	VALV 22382 + LIMI30774	1			
VWS GEMU	Auto diaphragm	VALV30197 + LIM I30774	1			
VWS GEMU	Auto diaphragm	VALV22383	2			
VWS GEMU	Auto Globe	726768	1			
VWS GEMU	Auto Globe	726771	1			
BWT	Ball Auto	726783	1			
BWT	Ball Auto	726785	1			
ALFA LAVAL	Float valve	726012	1			
DPL	Spring Check NRV	726762	2			
DPL	Manual Butterfly	726765	1			
JOHN GUEST	Manual Ball	538785	4			
NMP	Manual Ball	466578	2			
PARKER	Solenoid	726569	1			
REALM PRODUCTS	Spring Check NRV	726763	1			

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*.

9.4.4 Data

9.4.4.1 Pressure Indicator

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
PI-1				
Supplier	VWS WIKA			
Model/Part No:	233.50.063			
Range (bar)	0 – 7			
Location	feed water inlet to softener			
PI – 2				
Supplier	VWS WIKA			
Model/Part No:	233.50.063			
Range (bar)	0 – 7			
Location	Softened feed water to cartage filter			
PI – 3				
Supplier	VWS WIKA			
Model/Part No:	233.50.063 ARTICLE 8354014			
Range (bar)	0 – 7			
Location	Softened feed water filter outlet			
PI – 4				
Supplier	VWS PARKER			
Model/Part No:	P3A – EA 12 BEBGP			
Range (bar)	0 – 7			
Location	Degasser air sweep feed pressure Indicator			

Comments:

Reviewed by		Date	

9.4.4.2 Pressure Transmitter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
Supplier	VWS E+H			
Model/Part No:	PMP46- RE23PBACDGD			
Quantity	6			
Range (bar)	0-10			

S. No	Location	Tag No.	Serial No
1.	Degasser Outlet	PS/PT-3	5A 011 20 1024
2.	CDIA Inlet	PS/PT-5A	5A 011 A 01024
3.	CDIB Inlet	PS/PT-5B	5A 0101 A 01024
4.	CDIA Outlet	PS/PT-6A	PMP46 – RE 23PBA CDGD
5.	CDIB Outlet	PS/PT-6B	PMP46 – RE 23PBA CDGD
6.	Purified Water Outlet	PS/PT-7	PMP46 – RE 23PBA CDGD

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.4.4.2 Pressure Transmitter (cont'd)

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
Supplier	VWS E+H			
Model/Part No:	PMP46- RE23SBACDGD			
Quantity	2			
Range (bar)	0-40			

S. No	Location	Tag No.	Serial No
1	High Pressure Pump (P01) Outlet	PS/PT-1	5700 1B 01024
2	RO Concentrate	PS/PT-2	5700 1E 01024

Comments:

Reviewed by		Date	

9.4.4.3 Temperature Transmitter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
Supplier	VWS E+H			
Model/Part No:	TR45- BF5B1S2HAPGA0			
Quantity	2			
Range (° C)	0-100			
Type	90 mm insertion depth; 4-20ma output			

S. No.	Location	Tag No.	Serial No
1	Feed Tank	TS/TT-4	FC5024 – 03
2	Recycle Line	TS/TT-5	FC5021 - 03

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.4.4.4 Conductivity/Temperature Indication

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
Supplier	VWS THORNTON			
Model/Part No:	200CR - 6222-1			
Quantity	2			
Range (uS/CM)	0-1999			
Location	Central Control Panel			

S. No	Location	Tag No.	Serial No
1	RO and CEDI Feed Water Line	CI-1/2	603090201
2	RO and CEDI Product Water Line	CI-3	603100207

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.4.4.4 Conductivity / Temperature Transmitter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
Supplier	VWS THORNTON			
Model/Part No:	243E-223			
Quantity	3			
Accuracy	Ressistivity : ± 0.1 Mho / cm Temp. : ± 0.1 °C			

S. No	Location	Tag No.	Serial No
1	PU – 1 Outlet	CS/TS-1	04020487
2	RO Outlet	CS/TS-2	04020752
3	Purified Water Outlet	CS/TS-3	04020569

Comments:

Reviewed by		Date	

9.4.4.5 Flow Meter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
Make	Endress + Hauser			
Range	85 – 250 V AC			
Serial Number	72011120000			
Location	Outlet of heat exchanger			

Comments:

Reviewed by		Date	

9.4.4.6 Flow Transmitter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
FS/FT 1				
Supplier	VWS GEMU			
Model/Part No:	3020 50D 33 010 4 P120 25000 LH			
Range (L/Hr)	25000			
Type	Turbine meter			
Serial Number	423429 A			
Location	Softened water flow			
FS/FT-2				
Supplier	VWS NIXON			
Model/Part No:	BNO 500L			
Range (L/MIN)	6-60			
Type	Turbine Meter			
Location	RO Concentrate recirculation line			
FS/FT-3				
Supplier	VWS NIXON			
Model/Part No:	BNO 500L			
Range (L/MIN)	6-60			
Type	Turbine Meter			
Serial Number	19184			
Location	RO Concentrate to drain			

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.4.4.6 Flow Transmitter (cont'd)

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
FS/FT-4				
Supplier	VWS NIXON			
Model/Part No:	BNO 1000L			
Range (L/MIN)	18-180			
Type	Turbine Meter			
Serial Number	18562			
Location	RO Permeate Line			
FS/FT-5				
Supplier	VWS NIXON			
Model/Part No:	BNO 250			
Type	Turbine meter			
Quantity	2			
Range (l/min)	2 to 20			

	Location	Tag No./Serial No
1	CEDI LXA Inlet	FS/FT 5A
2	CEDI LXB Inlet	FS/FT 5B

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.4.4.7 Flow Indicator/Switch

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
FI -1				
Supplier	VWS GEMU			
Model/part No:	807/50/D332114-1-73			
Type	VA ROFI			
Range (m^3/hr)	0 - 10			
Location	Softener feed water line			
FI -2				
Supplier	VWS TECHNIQUIP			
Model:	Flux line of /1/2"+adjustable switch			
Type	VA ROFI + Switch			
Range (l/min)	30-200			
Quantity	2			

S. No.	Location	Tag No /Serial No
1	Degasser Inlet	FI2A/FSL-1A
2	Degasser Inlet	FI2B/FSL-1B

Comments:

Reviewed by		Date	

9.4.4.8 Level switch

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Date
LSL 1				
Supplier	VWS E+H			
Model/Part No:	FTL50H- ATC2AC2G4C			
Range	0 – 30 bar			
Tag No/Serial No				
Location	Feed water Tank TK1 Low level			
LSL 2				
Supplier	VWS EMS			
Model/Part No:	EMS PT.NO. E115			
Tag No/Serial No				
Location	Salt level detection in Brine Tank			

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 GENERATION 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
Pressure Indicator	PI-1						
Pressure Indicator	PI-2						
Pressure Indicator	PI-3						
Pressure Indicator	PI-4						
Pressure Transmitter	PS/PT-1						
Pressure Transmitter	PS/PT-2						
Pressure Transmitter	PS/PT-3						
Pressure Transmitter	PS/PT-5A						
Pressure Transmitter	PS/PT-5B						
Pressure Transmitter	PS/PT-6A						
Pressure Transmitter	PS/PT-6B						
Pressure Transmitter	PS/PT-7						
Temperature Transmitter	TS/TT-4						
Temperature Transmitter	TS/TT-5						
Conductivity Indicator	CI-1/2						
Conductivity Indicator	CI-3						
Conductivity/Temperature sensor	CS/TS-1						
Conductivity/Temperature sensor	CS/TS-2						
Conductivity Indicator	CS/TS-3						
Flow Indicator	FI-1						

Comments:			
Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.5.4 (cont'd)

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
Flow sensor / Transmitter	FS/FT-1						
Flow sensor / Transmitter	FS/FT-2						
Flow sensor / Transmitter	FS/FT-3						
Flow sensor / Transmitter	FS/FT-4						
Flow sensor / Transmitter	FS/FT-5A						
Flow sensor / Transmitter	FS-FT-5B						
Flow Indicator	FI2A/						
Flow Indicator	FI2B/						
Flow switch	FSL1A						
Flow switch	FSL1B						
Level switch	LSL-1						
Level switch	LSL-2						

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 GENERATION 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
Piping downstream from Feed water Tank TK 1	JH&G order indent number	SS 316L electro polished to < 0.5 Ra				
Manual Diaphragm Valve						
Body	Valve Schedule, CE0469-S01	316 SS				
Diaphragm		EPDM/PTFE faced EPDM				
Auto Diaphragm Valve						
Body	Valve Schedule, CE0469-S01	316 SS				
Diaphragm		EPDM				
Conductivity / Temperature Sensors	Instrument Schedule CE0469-S02	SS 316 L				
Temperature Transmitter	Instrument Schedule CE0469-S02	SS 316 L				
Flow Sensors	Instrument Schedule CE0469-S02	SS 316L / PTFE Carbon				
Pressure Transmitters	Instrument Schedule CE0469-S02	SS 316				

Comments:

Reviewed by		Date	

9.7 Services Verification

9.7.1 Objective

To verify that all services required for the operation of the system are available and connected to system 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 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*.

9.7.4 Data

Services	Specified	Actual	Acceptable [Y/N]	Initial / Date
Feed Water to Purified Water generation skid	• Temperature: 10-30 *°C* • *Pressure:*3.5 *bar g* • Pipe Diameter: 40 mm	• Temperature: • *Pressure*: • Pipe Diameter:		
Instrument air to Purified water generation skid	• Pressure: *6 barg* • Temperature: <40 *°C* • Pipe Material: PE	• Pressure: • Temperature: • Pipe Material:		
Electricity	• Voltage: 415±10%V • Phases: 3 • Frequency: 50Hz±5%	• 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*.

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 for the instrument in Appendix 2 - 'Configuration 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 PLC Controller

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
CPU				
Manufacturer	SIEMENS			
Model	6ES7-315-2AF03-0AB0			
FEPROM	6ES7-951-0KG00-0AA0			
Back up Battery	6ES7-971-1AA00-0AA0			
Power supply	6ES7-307-1EA00-0AA0			
Operator Interface Modules				
Manufacturer	SIEMENS			
Model	MP 370			
Touch screen	6AV6-545-0DA10-0AX0			
Battery	W79084-E1001-B2			
CF Card	6AV6-574-2AC00-2AA0			
Additional devices				
Manufacturer	SIEMENS			
Modbus card	6E57 – 341 – ICH01 - OAEO			
Modbus driver	6E57 – 870 – IAB01 - OYAO			
TS adapter	6E57 – 972 – OCA33 - OXAO			
Modem	WESTERMO WETD – 32A – 4B			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Interconnections				
Manufacturer	SIEMENS			
Profibus connector	6ES7-972-0BA11-0AX0			
Profibus connector	6ES7-972-0BB11-0AX0			
Profibus cable	6XV1-830-0EH10			
Modem cable	RS COMPONENT 202 - 745			
Analog/Digital Input/output cards				
Manufacturer	SIEMENS			
Digital input	6ES7-321-1BL00-0AA0			
Digital output	6ES7-322-1BL00-0AA0			
40 Point connector	6ES7-392-1AM00-0AA0			
Analog input	6ES7-331-1KF01-0AB0			
Analog I/O card	6ES7-335-7HG01-0AB0			
40 Point connector	6ES7-392-1AJ00-0AA0			
Operator Interface Terminal				
Manufacturer	SIEMENS			
Model	MP370			
Serial No.	6 AV 6545 – ODA – 10 - OAXO			
Location	Elga Skid			
Identification Number	SL – T9N 66744			

Comments:

Reviewed by		Date	

9.9 Spare Parts List

9.9.1 Objective

To verify the availability of specified spare part lists

9.9.2 Method

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

9.9.3 Acceptance Criteria

Approved spare part lists must be available.

9.9.4 Data

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

Comments:

Reviewed by		Date	

9.10 Filter List

9.10.1 Objective

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

9.10.2 Method

Visually examine the filters used in the system are as listed in the SPECIFIED column in *Section 9.10.4. Data*. Relevant certificates and test reports must be available and attached as an *Appendix*. 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*.

9.10.3 Acceptance Criteria

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

9.10.4 Data

9.10.4.1 In-line Filter

		SPECIFIED	ACTUAL	Acceptable [Y / N]	Initial / Date
Description		Pore size: 5 µm			
Manufacturer		Domnick Hunter			
Model /Part No	Housing	VIL032CBE			
	Element	539920002			
Type		Cartridge			
No of filters		1			
Location		Downstream of Softener			
Material	Housing	316 SS			
	Element	PP			
Tag Number /Serial Number		FILT-1			
Verify Orientation		Vertical			

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

9.11 Visual Inspection

9.11.1 Objective

To verify that the Purified Water Generation System is ready for operation.

9.11.2 Method

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

9.11.3 Acceptance Criteria

The specifications listed in the SPECIFIED column are met.

9.11.4 Data

S. No.	SPECIFIED	Acceptable [Y/N]	Initial / Date
1.	Installation of Purified Water Generation System is completed.		
2.	Purified Water Generation 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 GENERATION 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	Spare Parts List		
9.10	Filter List		
9.11	Visual Inspection		

Comments:

Reviewed by		Date	

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

11. DEVIATION SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in …… 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 for …….., Capsules and Liquid Orals Manufacturing Facility, VMP/00, Revision 00.
- 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".

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

13. LIST OF ANNEXURES

Annexure No.	Document Title

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION SYSTEM

14. SUMMARY

INSTALLATION QUALIFICATION PROTOCOL FOR PURIFIED WATER GENERATION 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 GENERATION SYSTEM