OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

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

PREPARED BY:

Organization	Name	Designation	Signature	Date

CHECKED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

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OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

1. OBJECTIVE

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

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

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

2. SCOPE

This protocol covers all aspects of Operational Qualification for the Process Water Generation & Distribution serving the .....; Tablets, Capsules & Liquid Oral Manufacturing Facility. 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, and Serial Softeners with Brine Measuring Tank & Salt Saturation Tank, Soft Water Storage & Pumping System and Process Water Storage & Pumping System.

This protocol will define the methods and documentation used to qualify the Process Water Generation & Distribution System for OQ. Successful completion of this protocol will verify that the Process Water Generation & Distribution meets all acceptance criteria and is ready for Performance 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 OQ Protocol.
- Ensures that the protocol is in compliance with current .....policies and procedures.
- Ensures that the content is sufficient, clearly defined technically sound and accurate.
- Ensures compliance with design specifications.

Validation Personnel

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

- Overall cGMP compliance for OQ
- Review and Pre-Approval of OQ Protocol
- Execution of this OQ protocol

- Document Control of OQ Protocol until such document is completed, approved and after.
- Regulatory Compliance Review of the completed OQ Protocol
- Review and Approval of the executed OQ Protocol.

4. SYSTEM DESCRIPTION

The purpose of Process Water Generation & Distribution System is to generate Potable Water & Process Water for Potable water distribution system for Formulation, 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, Serial Softners with Brine Measuring Tank & Salt Saturation Tank, Soft Water Storage & Pumping System and Process Water Storage & Pumping System.

Process Water Generation & Distribution System has been ordered to the following vendors:

1. ION Exchange (India) Ltd.
2. Enmax System " Grundfoss"
3. AIPA Automation Pvt. Ltd.

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 softeners. Online NaHSo3 dosing is done on Potable Water coming from potable water transfer pump to remove dissolved chlorine in water. De-chlorination is carried out for water entering to softeners 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 serial softener 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.

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 OQ File should include:

- This OQ Protocol.
- Any laboratory test results or their referenced location.

- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

6. DATA COLLECTION

All personnel shall have suitable documented training or experience.

All approvals shall be made in *BLUE* ink.

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

All corrections to this Protocol, which are not retyped, are to be made in *BLUE* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.

After performing the qualification tests, collect all relevant printouts and certificates and retain for inclusion in the OQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Appendices* and to be listed in *Section 13. List of Appendices*.

7. CHANGE CONTROL

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

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

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

8. PRE-QUALIFICATION REQUIREMENTS

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

8.1 System Pre-requisites

S. No.	Description of Pre-requisite	Completed [Yes / No]	Verified By	Date
1	Verify that the IQ of the Process Water System has been executed and approved. IQ Protocol Document No: IQ/U/PSD-01	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Process Water System has been executed and approved.	Yes/No*		
3	Verify that the safety walk through has been completed and that the system is safe to use.	Yes/No*		
4	SOP-Process Water Generation &Distribution Operation	Yes/No*		
5	SOP- Process Water Generation & Distribution Maintenance.	Yes/No*		
6	SOP Process Water Generation & Distribution Cleaning /Washing	Yes/No*		
7	SOP- Process Water Generation & Distribution Calibration.	Yes/No*		

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

9. TESTS AND CHECKS

9.1 SOP Verification

9.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Process Water Generation & Distribution System.

9.1.2 Method

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

Ensure all SOP's identified in Section 9.1.4 are evaluated and checked.

9.1.3 Acceptance Criteria

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

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9.1.4 Results

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

SOP Number	SOP Description	SOP accurate after check [Y/N]	Initial / Date
Process Water Generation & Distribution Maintenance			
	Preventive Maintenance of MGF		
	Preventive Maintenance of Softener System		
Process Water Generation & Distribution Cleaning /Washing			
	Cleaning of Raw Water Storage tank		
	Cleaning of Filtered Water Storage tank		
	Cleaning of Soft Water Storage tank		
	Cleaning of Process Water Storage tank		
Process Water Generation & Distribution Calibration			
	Calibration of Conductivity indicator		
	Calibration of pH Analyser		
	Calibration of Pressure transmitter		
	Calibration of Chlorine Analyser		
	Calibration of Flow indicator		
	Calibration of Conductivity sensor		
	Calibration of Temperature transmitter		

Comments:

Reviewed by		Date	

9.2 System Start-Up and Shutdown Test

9.2.1 Objective

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

9.2.2 Method

Follow instructions in the Test Method column of section 9.2.4 to test the start-up and shutdown of each system component. Obtain approval from the Production, Electrical and Mechanical Departments (where applicable) prior to this test and attach the approval slip as an appendix to this protocol. Record all observations in section 9.2.4 and attach any raw data printouts as an appendix to this protocol.

9.2.3 Acceptance Criteria

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

Specific acceptance criteria for each test are provided in the tables in section 9.2.4.

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.2.4 Results

Shutdown Procedure

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
While the system is operating, cease operation by assigning the following mode on the Electrical & Local Instrument Control Panel				
Stop Pump	Reading drops to zero			
Stop Pump	Reading drops to zero			
Stop Pump	Reading drops to zero. Online Chlorine dosing system to stop after interval of time to be defined during operational qualification.			
Stop Pump	Reading drops to zero			
Stop Deep Bore well	Reading drops to zero Online chlorine dosing system to stop after interval of time to be defined during operational qualification.			

Equipment Operated by		Date	

Comments:
- **Ensure Purified Water System is not running/has sufficient water in storage tank, so as not to impact operation of Purified Water System.**
- **Since Process Water Generation & Distribution system being operated & controlled through Local Instrument Panel & Electrical MCC therefore shutdown shall be done manually.**

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.2.4 Results (cont'd)

Power-Up and Start Test

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switch on Local Instrument Control Panel				
Start Deep Bore well	Gives reading Online Chlorination System starts			
Start Pump P-800 A/B if LALL 801 & LALL 802 is off. If LALL 801 & LALL 802 is on then wait for some time till automatically switches off.	Gives reading			
Start Pump P-801 A/B if LIAL 806 is off. If LIAL 806 is on then wait for some time till automatically switches off.	FIQ 808 gives reading Online De-chlorination System (X-803) & Online Chlorination System (X-805) starts.			
Start Pump P-804 A/B if LALL 810 is off. If LALL 810 is on then wait for some time till automatically switches off.	FIQ 803 gives reading			
Start Pump P-1401 A/B if LAL 1401 is off. If LAL 1401 is on then wait for some time till automatically switches off.	PI 1401 gives reading			

Equipment Operated By		Date	

Comments:
Since Process Water Generation & Distribution system being operated & controlled through Local Instrument Panel & Electrical MCC therefore shutdown shall be done manually.

Reviewed by		Date	

9.3 System Functionality Tests

9.3.1 Objective

To verify Process Water Generation & Distribution System components functionality.

9.3.2 Method

Prior to this test, power up and start-up each component as described in Section 9.2.4: *Start Up and Start Test*. Operate each item as described in Section 9.3.4 to test the functionality of the system. Record all observations in the Actual Results column in Section 9.3.4.

9.3.3 Acceptance Criteria

All aspects of control for individual components integrated within the Process Water Generation & Distribution System shall function as specified in the expected results column in Section 9.3.4.

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.3.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switching on the Power and Utilities to the System				
Switch on the power and utilities to the system	System is ready to start			
Monitor and log the reading	Log the following reading - Voltage 415 ± 10% V. - Compressed air pressure-6 bar			
Deep Bore well				
1.Switch OFF Deep Bore well	PI 801 A/B reading drops to zero FI 812 reading drops to zero Online Chlorination System (X-801) stops			
2.Switch ON Deep Bore well	Log the following reading - PI 801 A/B reading - FI 812 reading Check weather Online Chlorination System (X-801) starts			
On line Chlorination System (X-801)				
Set proportionate Dosing System Chlorine content. Monitor quantity of Water fed in 1 hr. Measure the level of NaOCl in dosing tank at the start and end of Cycle Manually calculate the amount of NaOCl dosed and hence calculate free chlorine in Water.	Amount of free chlorine Amount of NaOCl dosed			
Raw Water Transfer Pumps (P-800 A/B)				
1. Switch OFF Raw Water Tr. Pumps P-800 A/B	PI-802 A/B reading drops to zero PI-806 reading drops to zero PI 807 reading drops to zero			
2. Switching ON Raw Water Tr. Pumps P-800 A/B	Log the following - PI-802 A/B reading - PI-806 reading			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.3.4 Results (cont'd)

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Dual Media Filter (X-802)				
1. Ensure Raw Water Tr. Pumps P-800 A/B are running	Log the following reading - PI-806 reading - PI-807 reading Calculate manually Differential Pressure across dual Media Filter and check whether it is with in range			
On line De-Chlorination System (X-803)				
Set Dosing Chlorine Content. Monitor quantity of water fed in1 hour thru FIQ –808. Measure the level of Sodium Meta Bi-Sulphate (SMBS) at the start and end of cycle. Manually calculate amount of SMBS dosed and hence calculate free chlorine in water.	Amount of free chlorine			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.3.4 Results (cont'd)

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Potable Water Tr. Pump				
1. Switch OFF Potable Water Tr. Pump P-801 A/B	PI-803 A/B reading drops to zero FIQ-808 reading drops to zero			
2. Switch ON Potable water Tr. Pump P-801 A/B	Log the following - PI-803 A/B reading - FIQ –808 reading Online De-Chlorination system (X-803) starts			
Softener (X-804)				
1. Initiate manual regeneration. Record the stages of regeneration.	Regeneration starts and continues in an automatic sequence as, without any fault alarm listed below: 1. Media backwashing. 2. Brine solution dilution. 3. Passing brine through media. 4. Displacing regenerant and hardness salt. 5. Rinsing excess brine solution. 6. Completion of regeneration			
2. Initiate Automatic regeneration by simulating the volume of soft water produced. Record the stages of regeneration.	Regeneration starts and continues in an automatic sequence as, without any fault alarm listed below: 1. Media backwashing. 2. Brine solution dilution. 3. Passing brine through media. 4. Displacing regenerant and hardness salt. 5. Rinsing excess brine solution. 6. Completion of regeneration			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.3.4 Results (cont'd)

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
On line Chlorination System (X-805)				
Sets proportionate dosing system chlorine content. Monitor quantity of water fed in 1 hour thru FIQ-808 Measure the level of NaOCl in Dosing Tank at the start and of cycle. Manually calculate the amount of NaOCl dosed and hence calculate free chlorine in water.	Amount of free chlorine			
Process Water Tr. Pump (P-804 A/B)				
1. Switch OFF Process Water Tr. Pump P-804 A/B	PI-805 A/B reading drops to zero FIQ-803 reading drops to zero Online Chlorination System (X-805) gradually stops after some time.			
2. Switch ON Process Water Tr. Pump P-804 A/B	Log the following - PI-805 A/B reading - FIQ –803 reading			
Process Water Tr. Pump (P-1401 A/B)				
1. Switch OFF Process Water Tr. Pump P-1401 A/B	PI-1401 A/B reading drops to zero			
2. Switch ON Process Water Tr. Pump P-1401 A/B	Log the following - PI-1401 A/B reading			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

9.4 System Alarm and Interlocks Test

9.4.1 Objective

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

9.4.2 Method

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

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

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

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

Attach a copy of the alarms and Interlocks test check sheet as an appendix to the protocol. Record all observations in the Actual Results in section 9.4.4 and attach any raw data printouts to the alarms and Interlocks test check sheet.

9.4.3 Acceptance Criteria

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

Alarm / Interlock retesting must activate in the correct situation and with the correct effect as described in the SAT document.
System cannot be started when critical alarms are activated.
Record of alarms/interlocks testing check sheet is attached in the appendix

9.4.4 Results - As indicated in Local Instrument Panel (LCP-01)

Item	Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
LIAL806	(Input the test method to trigger the alarm)	"Level T-801 A/B/C Low" flashing in Alarm Annunciator accordingly trips Pump P-801 A/B.			
LAH 801	(Input the test method to trigger the alarm)	"Level T-800 C High" flashing in Alarm Annunciator			
LAL 801	(Input the test method to trigger the alarm)	"Level T-800 C Low" flashing in Alarm Annunciator			
LALL 801	(Input the test method to trigger the alarm)	"Level T-800 CLowLow" flashing in Alarm Annunciator accordingly trips Pump P-800 A.			
LAH 802	(Input the test method to trigger the alarm)	"Level T-800 D High" flashing in Alarm Annunciator			
LAL 802	(Input the test method to trigger the alarm)	"Level T-800 D Low" flashing in Alarm Annunciator			

Equipment Operated by		Date	

Comments: **Process water Generation & Distribution system is operated through individual microprocessor indicator/ Integrator for each control parameter mounted in Local Instrument Panel (LCP-01)**

Reviewed by		Date	

9.4.5 Results - As indicated in Local Instrument Panel (LCP-01)

Item	Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
LALL 802	(Input the test method to trigger the alarm)	"Level T-800 D LowLow" flashing in Alarm Annunciator accordingly trips Pump P-800 B.			
LAH 808	(Input the test method to trigger the alarm)	"Level T-802 A High" flashing in Alarm Annunciator			
LAL 808	(Input the test method to trigger the alarm)	"Level T-802 A Low" flashing in Alarm Annunciator			
LALL 808	(Input the test method to trigger the alarm)	"Level T-802 A LowLow" flashing in Alarm Annunciator accordingly Pump P803A/B shall trips			
LAH 810	(Input the test method to trigger the alarm)	"Level T-802 B High" flashing in Alarm Annunciator			
LAL 810	(Input the test method to trigger the alarm)	"Level T-802 B Low" flashing in Alarm Annunciator			
LALL 810	(Input the test method to trigger the alarm)	"Level T-808 B LowLow" flashing in Alarm Annunciator accordingly trips Pump P-804 A/B.			

Equipment Operated by		Date	

Comments: **Process water Generation & Distribution system is operated through individual microprocessor indicator/ Integrator for each control parameter mounted in Local Instrument Panel (LCP-01)**

Reviewed by		Date	

9.5 Valve Operational Test

9.5.1 Objective

To ensure that valves located at throughout the Process Water Storage & Distribution System operates correctly and can be accessed safely.

9.5.2 Method

Locate each valve listed in Section 9.5.4. Perform the test by manually opening and closing the valve. Verify that all valves can be accessed safely and that each valve can be fully opened and closed. Record results following testing in section 9.5.4.

9.5.3 Acceptance Criteria

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

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.5.4 Results – Valves under Scope of ION Exchange (India) Pvt. Ltd.

Valve Check	Expected Result	Valve Tag No	Actual Result	Acceptable [Y/N]	Initial / Date
Verify that each valve can be assessed safely. Verify that each valve operates and seals correctly.	Valve can be accessed safely. Valves operate and seal correctly.	MGF V1			
		MGF V2			
		MGF V3			
		MGF V4			
		MGF V5			
		MGF V6			
		MGF V7			
		MGF V8			
		SF V1-A			
		SF V1-B			
		SF V2-A			
		SF V2-B			
		SF V3-A			
		SF V3-B			
		SF V4-A			
		SF V4-B			
		SF V5			
		SF V6			
		SF V7			
		SF V8			
		SF V9-A			
		SF V9-A			
		SF V9-B			
		SF V10-A			
		SF V10-B			
		SF V11			
		SF V12			

Equipment Operated by		Date	

Comments: **Please refer Valve Schedule in ION Exchange (I) Pvt. Ltd. Flow Diagram (Drg. No. HA2-D103040126-01-01, Rev A, Dtd. 21.02.205)**

Reviewed by		Date	

9.5.4 Results (cont'd) – Valves under Scope of .....

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

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

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.5.5 Results (cont'd) – Valves under Scope of .....

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

Equipment Operated by		Date	

Comments: **Please refer Jacobs H&G Pvt Ltd P&I Diagram For Water System**
(Drg. No.12-2862-00/P.01/0008/A1, Rev. F, Dtd. 02.08.05)
& P&I Diagram for Process Water System
(Drg. No. 12-2862-00/P.01/0014/A1, Rev. D , Dtd.02.08.05)

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.5.5 Results (cont'd) – Valves under Scope of ……..

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

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

9.5.5 Results (cont'd) – Valves under Scope of …….

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

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

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.5.5 Results (cont'd) – Valves under Scope of ……..

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

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.5.5 Results (cont'd) – Valves under Scope of ……..

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

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

9.6 Confirmation of Critical Parameter and Full Function Testing

9.6.1 Objective

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

- Chlorine content in the Raw Water from Deep Bore well to Raw Water storage Tank T-800 C/D
- Feed Water Pressure at inlet of Multi Grade Filter (X-802)
- Pressure drop across Multi Grade Filter (X-802)
- Feed water Free Chlorine is not more than __ ppm at Softener inlet
- Feed Water Pressure at inlet of Softener-I (X-804)
- Feed Water Pressure at inlet of Softener-II (X-804)
- Feed water Free Chlorine is not less than __ ppm at Soft water tank-II (T-802 B)

9.6.2 Method

Follow the test methods described in section 9.6.4 for various parameters under test.
Record the observation in 9.6.4 actual results column.
Attach supporting documents, as applicable, in the appendix.

9.6.3 Acceptance Criteria

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

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.6.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Chlorine content in the Raw Water from Deep Bore well to Raw Water storage Tank T-800 C/D				
Set proportionate dosing system chlorine content Monitor quantity of Water fed on 1Hr. Measure the level of NaOCl in dosing tank at the start and end of Cycle Manually calculate the amount of NaOCl dosed and hence calculate free chlorine in Water.	Amount of free chlorine			
Feed Water Pressure at inlet of Multi Grade Filter (X-802)				
Ensure Raw Water Transfer Pumps (P-800A/B) are running. Monitor and log the reading of PI 806.	PI 806 reading			
Pressure drop across Multi Grade Filter (X-802)				
Ensure Raw Water Transfer Pumps (P-800A/B) are running. Monitor and log the reading of PI 806 and PI-807. Manually calculate Differential Pressure across Dual Media Filter	Differential Pressure			
Feed water Free Chlorine is not more than 2 ppm at Softener inlet				
Set Dosing Chlorine Content. Monitor quantity of water fed in1 hour thru FIQ –808. Measure the level of Sodium Meta Bi- Sulphate (SMBS) at the start and end of cycle. Manually calculate amount of SMBS dosed and hence calculate free chlorine in water.	Amount of free chlorine			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

9.6.4 Results (cont'd)

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Feed Water Pressure at inlet of Softener-I (X-804)				
Ensure Raw Water Transfer Pumps (P-801A/B) are running. Monitor and log the reading of PG 3.	PG 3 reading			
Ensure Raw Water Transfer Pumps (P-801A/B) are running. Monitor and log the reading of PG 4.	PG 4 reading			
Feed water Free Chlorine is not less than 2 ppm at Soft water tank-II (T-802 B)				
Sets proportionate dosing system chlorine content. Close return line from Purified Water Generation System. Monitor quantity of water fed in 1 hour thru FIQ-808 Measure the level of NaOCl in Dosing Tank at the start and of cycle. Manually calculate the amount of NaOCl dosed and hence calculate free Chlorine in water.	Amount of free chlorine			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

10 CHECKLIST OF ALL TESTS AND CHECKS

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

Reference No.	Tests or Checks	Executed [Y/N]	Comment
9.1	SOP Verification		
9.2	Process Water Generation & Distribution System Start-Up and Shutdown Test		
9.3	Process Water Generation & Distribution System Functionality Test		
9.4	Process Water Generation & Distribution Alarm and Interlocks Test		
9.5	Process Water Generation & Distribution Valve Operational Test		
9.6	Process Water Generation & Distribution Confirmation of Critical parameter and full function testing		

Comments:

Reviewed by		Date	

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

11 VARIANCE SHEET

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

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Variance No.	Variance Title	Status

Comments:

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 APPENDICES

Appendix No.	Document Title

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

14 SUMMARY

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

OPERATIONAL QUALIFICATION PROTOCOL FOR PROCESS WATER GENERATION & DISTRIBUTION SYSTEM

15 APPROVALS

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

EXECUTED BY:

Organization	Name	Designation	Signature	Date

REVIEWED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date