STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification of Water System	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for Qualification of Water System.

2.0 SCOPE:

This SOP is applicable for qualification of water system at …….

3.0 RESPONSIBILITY:

3.1 Engineering officer/executive will be responsible to run the system efficiently and to regenerate and sanitize the system as per defined frequencies.

3.2 QC officer/executive will be responsible to analyze the samples of water as per sampling plan and to submit the analysis of water as established specification.

3.3 QA officer/executive will be responsible for monitoring of protocol completeness, accuracy, technical excellence, applicability, scheduling and conducting of Periodic Validation runs, data review and Re-Validation reports preparation.

4.0 ACCOUNTABILITY:

Head QA/QC shall be accountable for the compliance of this SOP.

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

Water system shall be qualified before use of water for pharmaceutical purpose in the plant**.**

6.1 Prequalification stages: Water system shall be qualified into the following stages:

6.1.1 Design qualification:

Documented verification that proposed design of the equipment/system is suitable for intended purpose.

6.1.2 Installation qualification:

6.1.2.1 To verify that the purified water/ water for injection generation storage and distribution system have been installed in accordance with the predefined acceptance criteria and meet cGMP requirements.

6.1.2.2 To establish that the equipments and components are as per specification and installed as per the approve design.

6.1.2.3 To verify that the requirements specified at the time of purchase are meet in the delivered and installed system/equipment.

6.1.2.4 Draft SOP's of system & operation shall be prepared during IQ.

6.1.2.5 Documented verification that the equipment/system complies with the approved design, the manufacturer's recommendation and user's requirement.

6.1.3 Operational Qualification:

6.1.3.1 To demonstrate that the equipment/system operates in accordance with URS & designed specifications and complies with relevant cGMP requirements.

6.1.3.2 To verify the operational features of Water Generation, Distribution and Storage System and to ensure that it produces desired Quality & Rated Output according to Designed Specifications.

6.1.3.3 To verify all the Operational features from User Point of View of Machine, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

6.1.3.4 To establish that entire system as a whole is functioning with respect to Electrical and Instrumentation as specified in DQ.

6.1.3.5 To confirm the suitability of the SOP's for all routine activities associated with the system.

6.1.3.6 Documented verification that the equipment/System perform as intended throughout the anticipated Operating range.

6.2 Water System Qualification/Qualification phases:

The Water System is qualified through various phases, includes**:**

Pre Qualification Stage : DQ, IQ and OQ stage

Performance Qualification :

Phase I **:** Study for two week (Short term)

Phase II **:** Study for two week (Intermediate)

Phase III **:** For one year (Long term control)

6.3 Start up of water system:

6.3.1 This stage starts after the Passivation of the System. In this stage the system is allowed to run for a few days in which the water generated is drained daily and new water is allowed to generate to the fullest capacity.

6.3.2 During this stage the Chlorination agent and De-chlorination agent, Sanitization frequency of the water system shall be established.

6.3.3 After that the following standard operating procedure (SOP) shall be prepared:

6.3.3.1 Operation and calibration of the online monitoring device.

6.3.3.2 Operation of the water system and its related components.

6.3.3.3 Dose of the chlorination and chlorination agent.

6.3.3.4 Sanitization frequency of the water system.

6.3.3.5 Operation and Calibration of analytical instruments.

6.3.3.6 Sampling of various grades of water for chemical and microbiological analysis.

6.3.3.7 Preventive maintenance procedure and frequency.

6.3.3.8 Cleaning frequency of storage tank.

Note: These SOP may be change during performance qualification of the system.

6.4 Establishment of the test specifications and method of analysis:

Prepare the test specifications and method of analysis.

6.5 Trainings:

Training should be given to the concerned persons.

6.6 Performance qualification of water system:

6.6.1 To verify that the purified water/water for injection generation, storage & distribution system is functional in accordance with the pre-defined acceptance criteria and meets cGMP requirements.

6.6.2 To verify the generation system is able to deliver volume as per installed capacity with proper flow in loop & at user point.

6.6.3 To verify quality of delivered end product as pre-defined acceptance criteria.

6.7 Water system qualification Phase-I:

This phase will be carried out for two weeks. During this period the system shall Operate continuously without failure or performance deviation. The following Procedures shall be included in the testing approach:

- Analysis of the water drawn from each user/sampling point shall be performed on daily basis.
- Undertake chemical and microbiological testing in accordance with Protocol.
- Sample or continuously monitor the incoming feed water to verify its quality.
- Sample or continuously monitor after each step in the purification process.
- Sample or continuously monitor at each point of use and at other defined sample points.
- Develop appropriate operating ranges.
- Develop and finalize operation, cleaning, sanitizing and maintenance procedures.
- Demonstrate production and delivery of product water of the required quality and quantity.
- Use and refine the Standard Operation Procedure for operation, maintenance, sanitization and troubleshooting.
- Trend shall be prepared for each test specification of each user/sampling point by QC and submitted to QA on completion of each Phase.
- Verify provisional alert levels.
- Develop and refine test-failure procedure.
- **After that report shall be prepared and contains the following details:**
- The minimum, maximum and average of each monitoring parameter
- Test specification and method of analysis followed
- The sanitization frequency followed during qualification
- Preventive maintenance frequency followed
- Deviations observed in any and corrective and preventive action taken, corrective and preventive actions shall be taken to rectify and avoid the recurrence of such problems.

Note: Water shall not be used in finished pharmaceutical product during phase-I qualification.

6.8 Water system qualification Phase-II:

- This phase shall be carried out for two weeks. Analysis of the water drawn from each user/sampling point shall be performed on daily basis.
- The sampling scheme shall be same as in phase-I.
- Water can be used for manufacturing purpose during this phase.
- Trend shall be prepared for each test specification of each user/sampling point by QC and submitted to QA on completion of each Phase.

6.9 Water system qualification Phase-III:

- Phase-III typically runs for 1 year after successful completion of Phase-II.
- Drawing of water distribution system.
- Dosing of chlorination and de-chlorination agent.
- Sample locations, sampling frequencies and tests should be reduced to normal routine pattern, based on established procedures proven during Phase-I and Phase-II.

6.9.1 Water can be used for manufacturing purpose during this phase which has the following objective and features.

- Demonstrate extended reliable performance.
- Ensure that seasonal variations are evaluated.

6.9.2 While reducing the frequency, consideration shall be given to monitor the critical points daily e.g. all the samples from the return loops, since this is representative sample of all the user/sampling points.

6.9.3 During the Phase –III of the water system, closely monitor the results and prepare the trend for each test specification of each user point by QC and submitted to QA.

6.9.4 Report shall contains the following details:

- The minimum, maximum and average of each monitoring parameter
- Test specification and method of analysis followed
- Deviations observed in any and corrective and preventive action taken, corrective and preventive actions shall be taken to rectify and avoid the recurrence of such problems.

6.9.5 After successful completion of the phase –III of the water system qualification, based on the observing sampling and analysis schedule shall be prepared for the continuous monitoring of the water system.

6.9.6 Establish the alert and action limits for the routine monitoring by statistical evaluation of data for each parameter during phase-III of water system qualification.

6.9.7 After completion of phase-III QA shall prepare yearly sampling schedule for water system under continues monitoring covering all user points.

6.10 REQUALIFICATION CRITERIA:

- Major Modification in Water System
- After any major breakdown

7.0 ABBREVIATIONS

PQ	Performance Qualification
SOP	Standard Operating Procedure
Sr. No	Serial Number
QC	Quality Control
QA	Quality Assurance

8.0 ANNEXURE:

Not Applicable

9.0 DISTRIBUTION:

- Master Copy — Quality Assurance Department
- Controlled Copy No. 01 — Head Quality Assurance
- Controlled Copy No. 02 — Head Quality Control
- Controlled Copy No.03 — Head Engineering

10.0 REFERENCE:

- In-House
- WHO TRS 970
- WHO TRS 937
- WHO TRS 929
- Bureau Of Indian Standards (IS 10500 : 1991)
- Indian Pharmacopoeia
- United States Pharmacopoeia

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		