



Pharmaceutical Water Facilities Qualification and Monitoring


Water is a limited resource and it's the most used raw material for the pharmaceutical industry, being used as an ingredient of the final product or for cleaning purposes.

The quality of pharmaceutical water has direct impact on the quality of the finished product. Therefore pharmaceutical water facilities must be designed, commissioned, qualified and maintained in order to guarantee the quality of water from its generation to distribution to each point of use. These activities imply an important workload and during qualification high peaks of work for internal quality control laboratories.

Eurofins provides a specific outsourcing solution, focused on facility pharmaceutical water qualification and monitoring. In addition to efficient sampling and analytical services a special attention is devoted to results interpretation and management, trend analysis and troubleshooting.

The full service for pharmaceutical water facilities comprises:

- Advisory services for qualification and validation protocols
- Water and steam sampling, performed by personnel qualified for pharmaceutical working areas and using specific SOPs and sampling materials for each type of water / analytical test.
- Full physico-chemical control of water according to Pharmacopeias EP, USP, JP (TOC, conductivity, nitrates, heavy metals, etc) or potability test.
- Microbiological control (total aerobic count and tests for specific microorganisms)
- Endotoxins testing (LAL test).
- Microbial identifications
- Customized studies for qualification of critical components of the facility
- Customized studies for validation of rapid microbiological methods



Eurofins experts give support to the manufacturer with a risk management based approach from an external and independent point of view along all the steps of commissioning, validation and monitoring of the pharmaceutical water facility:

- Checks and monitoring of critical points of the facility, before a full qualification program
- Validation protocols and sampling programs based on risk analysis
- Validation execution (OQ/PQ) and monitoring
- Assessment and definition of SOPs for OOT/OOS management and change controls
- Troubleshooting and assessment on preventive and corrective actions
- Trend analysis and interpretation of microbial identifications