Achieving Ultrapure Water Standards for Pharmaceutical Manufacturing with FEDI® Rx Fractional Electrodeionization

QUA®

Pure Technology

Client: Pharmaceutical Company (Guadalajara, Mexico)

Plant Capacity: 3,170 GPD (12 m^3/d)

Challenges:

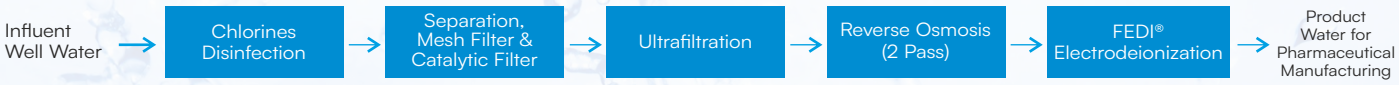
A rapidly expanding pharmaceutical company in Guadalajara, Mexico, required a new manufacturing facility to produce various medicines. The facility needed to be able to produce water with a conductivity (CE) of <1 µS/cm, total organic carbon (TOC) under 0.1 ppb, and silica concentrations below 1 ppm.

- The source water contained high levels of fluoride and hardness, requiring treatment to comply with Mexican and U.S. quality regulations.
- The water treatment equipment had to meet stringent standards and pass internal validation processes.
- The system required the capacity to withstand weekly sanitization with hot water at 85°C.

QUA's Solution:

- To address these challenges, the process includes pretreatment, followed by ultrafiltration (UF) and a two-pass reverse osmosis (RO) system, which is then paired with QUA's FEDI® Rx pharmaceutical-grade fractional electrodeionization system to produce a continuous flow of 0.5 m^3/hr of high-quality water.
- QUA's FEDI® Rx was chosen for its ability to consistently deliver ultrapure water up to 18 MΩcm using a patented process with double sets of electrodes per stack while maintaining the system's efficiency and integrity under rigorous operating conditions. The equipment was designed to remain operational continuously, preventing water stagnation and ensuring consistent water quality.

Flow Diagram:



Results:

The facility, including the water treatment system, has successfully passed all necessary validations and has been approved by the Mexican regulations to produce pharmaceuticals.

For over two years of operation, the FEDI® Rx system has consistently delivered water that exceeds the facility's quality requirements, with no reported issues. The produced water quality is higher than initially expected, meeting and surpassing the required CE, TOC, and silica levels, with a conductivity of <0.1 µS/cm.