

Location: United States



Applied Membranes transforms pharmaceutical manufacturing with USP-compliant ultrapure water system

Maintaining USP grade standards for water quality is essential in the pharmaceutical industry.

Challenge

The quality of water used in pharmaceutical manufacturing directly impacts the safety, efficacy, and regulatory compliance of pharmaceutical products. This includes water for injectables (WFI), hemodialysis, intravenous solutions, and other sterile pharmaceutical products.

A leading pharmaceutical and consumer healthcare company manufactures over-the-counter (OTC) medications, medical devices, and cosmetics.

The company needed a water treatment system to produce ultrapure water (UPW) meeting strict USP (United States Pharmacopeia) standards, critical for its manufacturing processes.

Project timing was critical, as delays could disrupt production schedules. Additionally, the system needed to fit within a very confined footprint within the facility.

The company reached out to Applied Membranes for a solution.

Solution

Applied Membranes engineered, manufactured, and commissioned a state-of-the-art 2-pass Reverse Osmosis-Electrodeionization **RO-RO-EDI** USP system capable of producing **40 GPM (10 m3/h)** of ultrapure water.

AMI RO-RO-EDI system treats potable municipal city water and provides ultrapure water (UPW) for pharmaceutical use. The system includes sanitary UPW piping, tanks, and construction to ensure the highest standards of cleanliness and purity.

Comprehensive testing, including Factory Acceptance Testing (FAT), was completed at Applied Membranes' ISO-certified manufacturing facility to validate the system's performance and quality standards.

Before shipping, AMI system was disassembled and subsequently reassembled at the client's site to accommodate the compact footprint of their facility.

Key Components:

- Antiscalant
- Chemical injection system
- Water softeners
- Carbon filters
- UPW storage tanks
- Complete UPW loop with recirculation
- Interconnecting piping and electrical
- Remote monitoring
- Programmable Logic Controller (PLC)

Results

Applied Membranes designed and built a bespoke USP-compliant system producing ultrapure water for pharmaceutical applications.

Fast turnaround time: Delivery of AMI turnkey solution was expedited within 6 weeks.

Support and training: AMI technicians provided onsite support during the installation process, offering hands-on assistance, expertise, and training to enable a smooth transition.

Enhanced production: AMI system produces reliable supply of high-quality UPW, improving the client's manufacturing processes and productivity.

Quality assurance: AMI system is built to comply with USP requirements, mitigating risk of contamination in pharmaceutical production.

