

Pharmaceutical Industry



The Challenge

A multinational pharma company in Asia undertaking a rapid expansion needed to meet stringent USP 28 guidelines for high purity water for injectable. The existing chemically sanitisable RO-EDI system did not meet the demands of regulated markets and besides, required considerable maintenance. The customer sought a dependable system vendor for a new unit that would meet their need for high purity water, and entrusted Ion Exchange with the responsibility.

The Solutions

We recommended a Hot Water Sanitisable INDION High Purity Water (HPW) plant consisting of:

- Ultra filtration
- Softening
- Heat Sanitisable Reverse Osmosis (RO)
- Heat Sanitisable Ultra Filtration system

Since the customer was using surface water, UF was incorporated in pre-treatment to handle suspended solids and colloids. A heat sanitisable UF system was also offered as a polishing unit downstream of the EDI to remove endotoxins/bacteria from the product water. The factory acceptance test (FAT), witnessed by the customer, was ensured prior to dispatch of the RO-EDI plant.

Results

Conductivity < 1.25 TOC < 500 ppb Bacteria < 10 CFU / 100 ml Endotoxins < 0.25 EU/ml

- Chemical-free sanitisation and virtually maintenance-free system
- Less manpower required due to high degree of automation
- Extensive validation documentation made periodic USFDA audits effortless for the customer