

## **INDION** High Purity Water Generation & Distribution

Complete integrated solution, specially designed for the pharma industry by the leading total water management company



**INDION** RO-EDI Systems

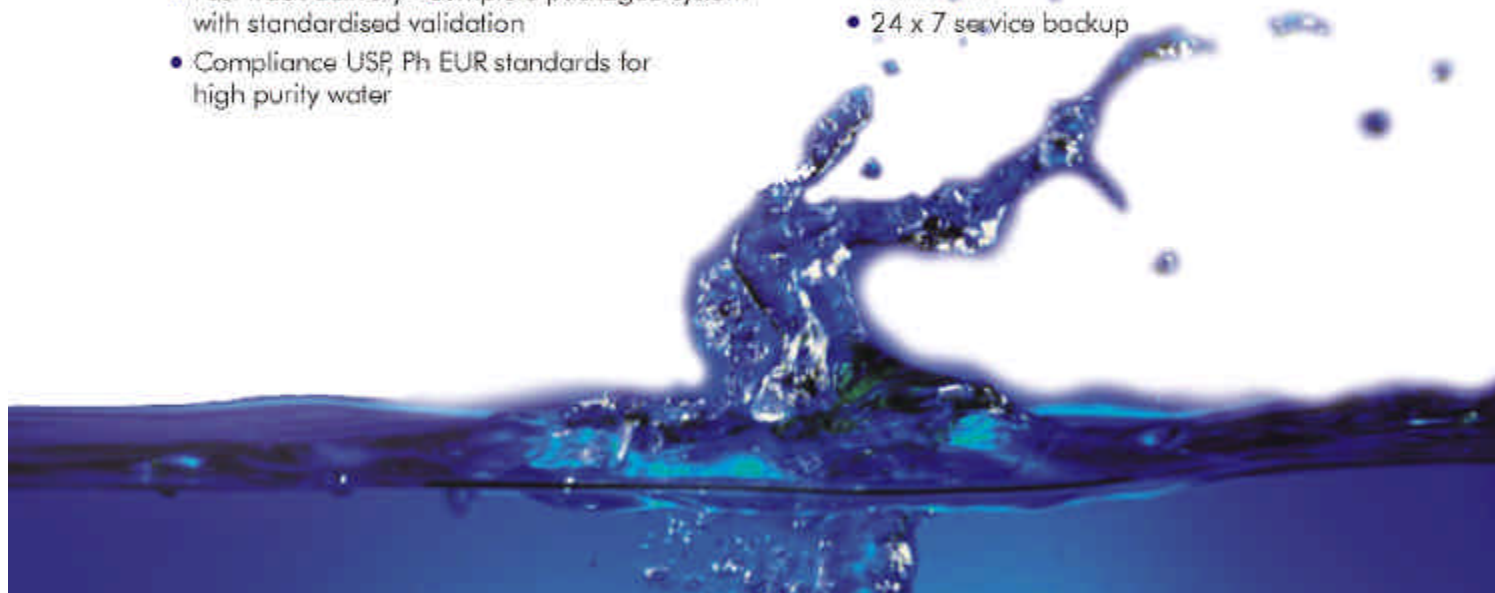


**INDION** Duo Rapide Demineralisers

Purified water, highly purified water, pyrogen-free water and water for injection are critical to the pharma industry's processes. Technological expertise and R&D capabilities combined with our close association with the industry enables us to deliver customised, speciality systems to meet stringent requirements for high purity water generation and distribution.

### **INDION** High Purity Water Systems offer:

- Complete water generation and distribution
- Hot water sanitisation for INDION RO-EDI
- Fast track delivery - complete packaged system with standardised validation
- Compliance USP, Ph EUR standards for high purity water
- Pre-validated to industry accepted standards
- Compliance to cGMP, GAMP & ISPE design standards
- 24 x 7 service backup



## Specifically for Pharmaceutical Industry

### Identify Customer Needs

Designed in consultation with pharmaceutical engineers and end users.



### Develop User Requirement Specification (URS)

The URS describes clearly and accurately what the industry requires from the system.



### Functional Design Specification (FDS)

The FDS describes the functions the system will perform and the facilities required to meet the specification.



### Design Qualification (DQ)

The DQ provides documented evidence that the key aspects of the design adhere to the URS.



### Hardware & Software Design Specifications (HDS/SDS)

The HDS & SDS describe the hardware and software components and their arrangements including the PLC.



### Installation & Operation Qualification (IQ/OQ)

The IQ and OQ provide documented evidence that the system is installed and performs as intended.



### **INDION** High Purity System

The result is a fully pre-validated system that is compliant with pharmaceutical standards.



### Hot Water Sanitisation



- Automatic microbial control
- Specification compliance assured
- No chemicals required

### Packaged System



- Fast track project delivery
- Minimum site disruption
- Footprint optimisation

### Standard Pre-validated System



- Reduced cost of compliance
- Complete FAT pre-delivery
- Provisional IQ at our factory

### Designed for Pharmaceuticals



- cGMP and GAMP compliance
- FDA compliance
- SS 316L construction
- Sanitary fittings
- Flexible automation and control
- Designed for accessibility

### Applications



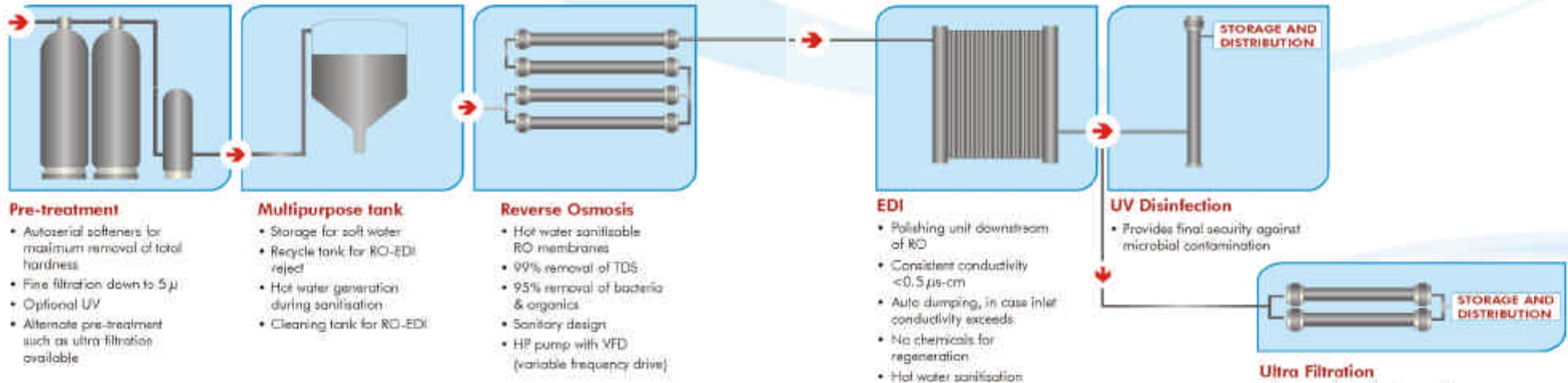
- Large and small volume parenterals
- Serum/media
- Genetically engineered drugs
- Ophthalmic solutions
- Antibiotics
- Cosmetics
- Veterinary products
- OTC and ethical products
- Fermenter make-up
- Medical devices
- Nutraceuticals
- Diagnostics
- Electronics
- Semi-conductors





## Complete, Wide Range & Integrated High Purity Package

### INDION RO-EDI Systems



### INDION Duo Rapide Demineralisers

#### Pre-treatment

- Ultra filtration uses advanced membrane technology & removes suspended solids from raw feed water

#### Features

- Instantaneous flow rates upto 70.5 gpm
- Automatic PLC control with continuous display readout of system status
- Short cycle (4 hours), rapid regeneration (30 min)
- High chemical efficiency, smaller footprint and higher flow rates than conventional plants
- Near neutral effluent reduces disposal costs

#### Duo Rapide Demineralisation

- Uses state-of-the-art ion exchange technology
- Conductivity <math>< 1 \mu\text{s-cm}</math>, with low running costs

#### TOC Removal

- Reverse osmosis/ Ultra filtration-UV steriliser



INDION Duo Rapide Demineralisers



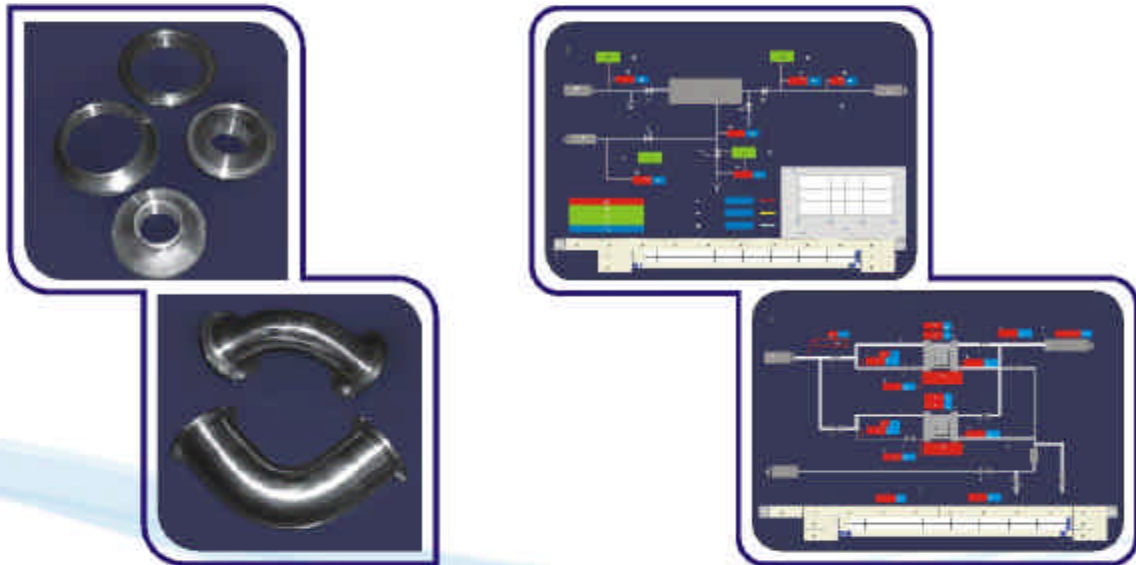
STANDARD PRE-VALIDATED SYSTEM

INDION RO-EDI Systems

#### Ultra Filtration

- Provides physical barrier and removes endotoxins & bacteria
- Produces highly purified water

## **INDION** Storage & Distribution Systems



**INDION** Distribution Systems

**SCADA**

A reliable and validated purified water generation plant is still half the job done.

The next big challenge after generating purified water is to distribute it at various user points across the factory at desired time, capacities, temperature and, most importantly, at desired quality. INDION Storage & Distribution Systems are designed considering cGMP norm, ISPE guidelines with respect to material of construction, orbital welding techniques, dead lag consideration (<2d), advanced instrumentation and controls. All the controls are monitored by advanced SCADA systems which are 21 CFR Part 11 compliant.

### **Features**

- High quality SS 316L electropolished storage tank with spray ball; vent filters of 0.2  $\mu$  and necessary fittings
- Pharma grade UV sterilisers with intensity monitor & hour meter in SS 316L construction
- Boroscopy facility for welds made
- Zero dead lag valves with EPDM or PTFE gaskets
- Critical instrumentation like level indicators, Compound pressure gauges, conductivity monitors, flow transmitters of reputed makes
- Combined SCADA system for water generation & distribution which are 21 CFR compliant
- Hot water sanitisation at > 80°C
- Imported PVDF/SS 316L tubes with original certificates with mill finish <0.8  $R_a$ , after EP <0.5  $R_a$
- All pumps, UV steriliser & fittings in sanitary construction
- Orbitally welded with printout facility
- Built around ISPE and cGMP guidelines

The components used in the distribution system are carefully selected depending on whether it is a chilled water loop, ambient loop or hot loop. Normally chilled or ambient loops would be for purified water while hot loops would be for WFI, unless high temperature is required at user purified water.



## Technical Specifications

### INDION RO-EDI Systems

Model		400	1000	1500	2000	3000	4000	6000
Product flow	gpm	1.76	4.4	6.6	8.8	13.2	17.6	26.42
Feed flow	gpm	2.34	5.86	8.8	11.73	17.6	23.47	35.22
Concentrate flow	gpm	0.58	1.46	2.2	2.93	4.4	5.87	8.8
Average Recovery	%			75				

Nominal flows are based on operation at 25°C, 500 mg/l TDS, 20 mg/l CO<sub>2</sub>, and SDI < 3.

Product flows at a maximum outlet pressure of 1 bar

RO-EDI systems can be made up to 52.90 gpm

#### Treated water quality

Purified Water Outlet of EDI < 0.5 µs-cm, < 250 ppb TOC, < 50 cfu/ml

Highly Purified Water Outlet of UF < 0.5 µs-cm, < 250 ppb TOC, < 10 cfu/100ml, < 0.25 E.U./ml

Treated water quality is dependent on feed water quality & flow rate

### INDION Duo Rapide Demineralisers

Model	1+	2+	3+	4+	5+	6+
Max. flow (gpm)	9.9	16.59	23.1	33.02	52.9	70.5
Conductivity (µs-cm)	0.1-1	0.1-1	0.1-1	0.1-1	0.1-1	0.1-1
pH	5-7	5-7	5-7	5-7	5-7	5-7

To the best of our knowledge the information contained in this publication is accurate. Ion Exchange LLC maintains a policy of continuous development and reserves the right to amend the information given herein without notice.