

# **INDION**<sup>®</sup> High Purity Water Systems

INDION High Purity Water (HPW) Systems are designed to meet the stringent requirements of the pharmaceutical industries and have been developed after consultations with the pharmaceutical engineers and end users. The net result is a fully pre-validated system that is compliant with the Current Good Manufacturing Practices (CGMP) and Good Automated Manufacturing Practices (GAMP) and FDA compliant.

#### The system includes

- INDION water softener and microfiltration (MF) for preconditioning the process feed water.
- Multipurpose tank of SS construction designed to minimize microbial contamination and provide for water storage, hot water sanitization and chemical cleaning capabilities.
- Reverse Osmosis (RO) unit to remove upto 97% of Total
- Dissolved Solids and over 99% of total dissolved organics and particulate matters. RO also provides total removal of microbial species.

Continuous Electro Deionization (CEDI) to remove boron and weakly ionized species like silica and carbon

 dioxide and produce high purity water with resistivity exceeding 18 mega ? cm at 25?C.

Ultrafiltration (UF) system (optional) to remove endotoxins and bacteria from the product water t o produce highly purified water.

• Ultraviolet (UV) disinfection system (optional) provides a high transmissvity medium that allows the UV to effectively kill any trace microbial species.

### **Features**

#### Hot Water Sanitization

- Provision for hot water sanitization
- No chemical requirement

#### **Packaged System**

• All the units are skid mounted for minimal foot print and easy installation and commissioning.



#### Designed for pharmaceutical industry

- Compliance with Current Good Manufacturing Practices (CGMP) and Good Automated Manufacturing Practices (GAMP).
- Compliance with Food and Drug Authority (FDA), International Society for Pharmaceutical Engineering (ISPE) and EU Pharmacopia (Ph. Eur) standards.
- All standards are of sanitary design.

#### Standard pre-validated system

- Pre-validation to industry accepted standards.
- Pre-delivery Factory Acceptance Testing (FAT)
- Provisional Installation Qualifications (IQ) at our factory.

#### **Ultimate Process Security**

- Multi-stage monitoring.
- Automated hot water sanitization at 85°C.
- Pass code PLC security.
- Advanced CEDI purification technology.

#### Designed for serviceability

- Easy access design.
- PLC information download facility.
- Performance qualification option for system validation.
- Inter-stage sampling capability.
- Automated membrane condition alarm.
- Full range of service maintenance contracts.

**Treated water quality:** Resistivity at 25°C Greater than 18 mega  $\Omega$  cm; Total Organic Carbon (TOC) Less than 100 ppb Total Bacterial Count (TBC) Less than 10 CFU / 100 ml

## **Specifications**

- One INDION Softener complete with frontal pipe work & valves and initial charge of ion exchange resin
- One Microfiltration MF unit
- One Multipurpose Tank of SS 316 L construction
- One RO unit complete with high pressure pump, membranes and other accessories
- One Continuous Electro Deionisation (CEDI) unit
- One Ultrafiltration unit (optional)
- One Ultraviolet unit (optional)
- One lot Sanitary fixtures

### **Applications**

Pharmaceutical industries involved in the manufacture of:

- Large and small volume parenterals
- Serum/media
- Genetically engineered drugs
- Opthalmic solutions
- Antibiotics
- Cosmetics & Neutraceuticals
- Veterinary products
- OTC and ethical products
- Fermenter make-up
- Diagnostics & Medical devices

#### **Technical Specifications**

Model Number		400	1000	1500	2000	3000	4000	6000
Product flow	l/h	400	1000	1500	2000	3000	4000	6000
Feed flow	l/h	533	1333	2000	2666	4000	5333	8000
Concentrate flow	l/h	133	333	500	666	1000	1333	2000
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

#### Our state-of-the-art manufacturing facilities are ISO 9001, ISO 14001 & ISO 45001 certified.

To the best of our knowledge the information contained in this publication is accurate. Ion Exchange (India) Ltd. maintains a policy of continuous development and reserves the right to amend the information given herein without notice. Please contact our regional / branch offices for current product specifications.

**INDION** is the registered trademark of Ion Exchange (India) Ltd.



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