Purified Water System

Pharmaceutical Water System

- Pre-Treatment
- PW–Purified Water System
- WFI–Multi-Effect Still
- WFI–Electrically Heated Multi-Effect Still
- PS–Pure Steam Generator
- PS–Electrically Heated Pure Steam Generator
- PS & WFI Combination
- PS/WFI–Storage & Distribution System
- HPW–EDI Skid
- Cold WFI –Integrated Membrane System For WFI
- CIP& SIP
- Mixing Vessel
- Double Tube Sheet (DTS) Shell & Tube Heat Exchanger

Purified & Highly Purified System

- Pre-Treatment System
- Reverse Osmosis Plant (**RO**)
- Nanofiltration Plant (**NF**)
- Ultra Filtration Plant (**UF**)
- Electro Dionization (**EDI**)
- Electrodialyzer (**ED**)
- Ion Exchanger (**IX**)
- Mixed Bed Plant (**MB**)

Laboratory Ultrapure Water Machine & Sewage Treatment Machine

- Plus-E2 UP Water Machine
- Plus-E3 UP Water Machine
- Fast-X3 UP Water Machine
- Integrated Sewage Treatment Equipment

Qirui Water Treatment

Complete Turn-Key Project

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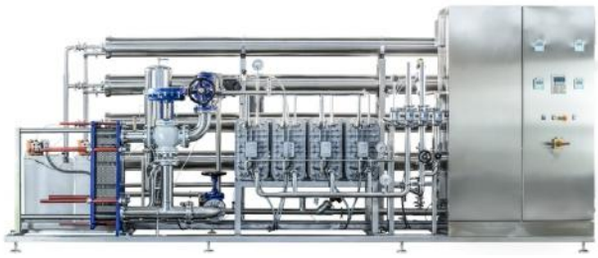
Pure Water Production Plant

Pure water generation plant is the result of many years of experience and constant technical development. They represent the simplest, safest and most reliable water purification method for the production of both purified and highly purified (endotoxin controlled) water for the pharmaceutical, cosmetic and food industry.



WFI Cold Generation System

Biocell' standard plant can cover a range of production from 300 to over 30, 000 liters per hour. All plants are in strict compliance with the relavent Pharmacopoeias.

Purification Optimisation

Biocell have always understood that large quantities of PW cannot be produced by a simple packaged unit. Variations in feed-water, customers' own standards and the specific use of the purified product *require* a dedicated design. Whether there is a preference is for dual stage RO or RO & EDI, chemical or hot water sanitisation, preferred instrumentation or a particularly high feedwater characteristic, the best system will always be designed according to these known requirements. Biocell have the largest configurable range to suit these requirements.

As well as the chosen process technology, a key characteristic of Biocell plant is that they are properly dimensioned to minimise non-productive time. By designing the system for proper regeneration and full use of each resin bed the systems can maximise their true production time whilst minimising replacement costs.

Comparison of Purification Technique

Biocell are equally able to provide all the variations of PW generation summarised in the below table which enables us to advise our customers on the most appropriate technology for their application without prejudice.

	Ion Exchange	RO Double	RO / EDI	Distillation by VC
Lifecycle Costs				
Capital Cost	▲	▲▲	▲▲	▲▲▲
Chemical Handling	▲▲▲▲	▲	▲	▲
Energy Consumption	▲	▲▲	▲▲	▲▲▲
Water Consumption	▲	▲▲	▲▲	▲
Maintenance	▲▲+	▲	▲+	▲
Purified Water Product				
Conductivity µS/cm @25°C	0.06 – 1.1	0.5 – 1.1	0.06 – 1.1	0.1 – 1.1
TOC (ppb)	>500	< 100	< 500	< 100
Bacterial Performance	Low	< 5 CFU/ml	< 100 CFU/ml	< 0.1 CFU/ml
Endotoxin	N/A	< 0.25 EU/ml	N/A	< 0.25 EU/ml

In our judgement that the most reliable solution for PW production for the pharmaceutical industry is dual stage RO.

Feedwater Pre-treatment Design

At the core of an optimally functioning system will be the pre-treatment design. Biocell will design the system according to the feedwater quality analysis data, using proven components such as:

- Sand and multimedia filter
- Micro filtration system
- Ultra-filtration system
- Organic scavenging
- Chemical dosing system
- Activated carbon filter
- Duplex softener
- De-aerator
- Break-tank
- Chemical and thermal sanitisation
- UV destructor
- Recirculation loops

Inadequate components or size can result in reducing availability and reducing the service life of RO membrane / EDI module. Biocell manufacture and test the complete system in our factory.

Biocell

Purified Water System

Services

Biocell, like our suppliers are solely dedicated to the regulated pharmaceutical sector. This enables us to fully understand not only the quality of performance required, but the documented evidence of all activities.

Project Management

A dedicated Project Manager follows each sale through to OQ handover. Liaison with customers, suppliers and field operations team to ensure effective project delivery.

Project Sitework

From our highly trained team offering:

- Installation Assistance
- Start-up & Commissioning
- SAT, IQ/OQ
- Calibration
- Thermal Mapping
- Cycle & Process Development

After-Sales

Full life-time support for equipment including:

- Full Training Packages
- Technical & Process Support
- Spare Parts Supply
- Preventative Maintenance
- Calibration
- Routine Validation
- Upgrade and Revamping

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Design & Build Standards

Purification plants are entirely made of AISI304/316L with surface mechanically polished.

Pre-treatment skids adopt either FDA compliant plastic or AISI316L for heat sanitisable version.

All the components, instrumentations included are from Industry reference suppliers, fully sanitary where appropriate.

Fully automatic control with Siemens S7-200 / TP series as the default hardware. Software is designed by Biocell according to GAMP guidelines and 21 CFR Part 11 where required.

The documentation packages supplied by Biocell for their plants are designed to allow complete validation of the system according to GDP and GMP rules. Full validation and calibration protocols are also available.

Full Turn-Key Supply

A major reason for Biocell success is their ability to provide a full turn-key package, including a comprehensive process guarantee covering the complete generation, storage and distribution where provided by them.

Items that can be included in the supply are:

- Pre-treatment
- Purified water generation
- Purified water storage and distribution
- WFI generation
- WFI storage and distribution
- Pure Steam Generation
- Full controls / SCADA system for complete supply

The supply includes feasibility/concept studies, project management, all engineering design, FAT, installation, start-up, SAT, calibration, IQ , OQ and customer training.

The integrated approach can not only save costs, but also important time to operations and offers complete peace-of-mind to clients' engineers, validation and purchasing departments.

PW TANK

PW SKID

Storage & Distribution

The PW storage and distribution SKID features professional modular design, which is characterized with reasonable and compact structure, pleasant appearance, convenient daily maintenance and operator-friendliness. It can be customized according to users' requirements. Based on the clients' requirements, the system can be designed with multiple sterilization modes, such as hot water sterilization, ozone sterilization, pure steam sterilization or 121℃ superheated water sterilization. The pump, heat exchanger, valves, pipe, instruments and other main components selected for the equipment are all well-known brands around the world, which can ensure the stable operation of the system in a long term. The program is optimized in accordance with GAMP5, which improves the stability of the program and complete documentation system to ensure the traceability of the system. To check whether the PW system can stably produce PW that meets the quality requirements in various circumstances in the future, the system will be subjected to the main verification and testing activities including Risk Assessment (RA)/Design Qualification (DQ)/Installation Qualification (IQ)/Operation Qualification (OQ). The system can fully meet the requirements of FDA cGMP, EU GMP, WHO GMP and SFDA GMP.

A *full* lifetime support.

Biocell