

Storage & Distribution System

Loop of Purified Water (PW) and Water For Injection (WFI)

The use of purified water (PW) and water for injection (WFI) in the production processes is very common in the pharmaceutical industry. These systems are represented by two main stages: water production and its storage and distribution. The assembly consisting of a storage tank and a distribution loop is called a purified water (PW) loop or a water for injection (WFI) loop. The difference between the purified water (PW) and water for injection (WFI) is mainly based on their physical, chemical and microbiological properties.

Main Features

- ◆ Single skid space saving design
- ◆ Polypropylene or pharmaceutical grade 316L stainless steel tubing and <25Ra wetted surface
- ◆ All welds visually inspected tri-clamp connections aid in sanitary design
- ◆ Sanitary horizontal multistage pump
- ◆ Sanitary heat exchanger / trim cooler
- ◆ SUS316L Storage Tank with heat traced vent filter
- ◆ Ozonated or hot water sanitization for microbial control

Typical Application

- ◆ Purified water (PW)
- ◆ Water for injection water (WFI)
- ◆ Highly purified grade water for rinsing (HPW)



Electrical Instrumentation

- ◆ 10.4" colour touchscreen HMI main control panel
- ◆ USB port for data logging & optional printer hook up
- ◆ Ethernet compatible for remote monitoring and troubleshooting
- ◆ Control panel powers up and interlocks pre-treatment via quick connect

Options

- ◆ Online TOC analyzer for real time TOC analysis
- ◆ NIST traceable sensor
- ◆ Upgrade to SUS304 skid and panel enclosure
- ◆ Duplex distribution pump
- ◆ IQ, OQ, SAT documentation



Key Criterias

- No stagnant condition and area of low flow rate
- Temperature control
- Proper slope of the pipeline to ensure drainability
- Stainless steel surface finish with appropriate roughness in order to avoid nutrient and biofilm accumulation
- No deadlegs area
- Periodic sanitisation or sterilisation of the storage tank and loop
- Storage tank protected with 0.2 micron hydrophobic vent filter
- Sufficient instrumentation and monitoring equipments



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

www.qiruiwater.com

Biocell

Storage & Distribution 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



PW TANK

The PW tank is manufactured in accordance with ASME BPE standards. The product can be designed according to clients' requirements in the form of atmospheric pressure vessel or pressurized vessel. The part in contact with PW is made of 316L stainless steel, and other parts (including frame) are made of 304 stainless steel. The tank is wrapped with insulation layer, which is made of the insulation material free of asbestos and chlorine. The insulation layer in turn is covered with 304 stainless steel shell. The inner wall of the tank is electro-polished, and the outer wall is hairline finished. The interface on the side wall of the tank is N/A connection to avoid dead legs. The tank is fully equipped with accessories, such as manhole, vent filter, spray ball, diaphragm pressure gauge (pressure transmitter), temperature sensor, level sensor and bursting disc.



PW SKID

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°C 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.

WFI TANK

The WFI tank is manufactured in accordance with ASME BPE standards. The product can be designed according to clients' requirements in the form of atmospheric pressure vessel or pressurized vessel. The part in contact with WFI is made of 316L stainless steel, and other parts (including frame) are made of 304 stainless steel. The tank is wrapped with insulation layer, which is made of the insulation material free of asbestos and chlorine. The insulation layer in turn is covered with 304 stainless steel shell. The inner wall of the tank is electro-polished, and the outer wall is hairline finished. The interface on the side wall of the tank is N/A connection to avoid dead legs. The tank is fully equipped with accessories, such as manhole, vent filter, spray ball, diaphragm pressure gauge (pressure transmitter), temperature sensor, level sensor and bursting disc.



WFI SKID

The WFI storage and distribution Skid features professional modular design, which is characterized with reasonable and compact structure, pleasant appearance, convenient daily maintenance and operator-friendliness. According to the actual requirements of clients and the operation mode of different dosage forms, the system can be designed for various operation modes, such as high temperature storage and high temperature circulation, high temperature storage and low temperature circulation, low temperature storage and low temperature circulation, with the purpose to conserve energy and reduce emission. The system can be designed with multiple sterilization modes, such as pure steam sterilization or 121°C superheated water sterilization. The pump, heat exchanger, valve, 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 WFI system can stably produce WFI 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.