Line-Link
Machinery Total Solution

Pharmaceutical Water System Catalogue

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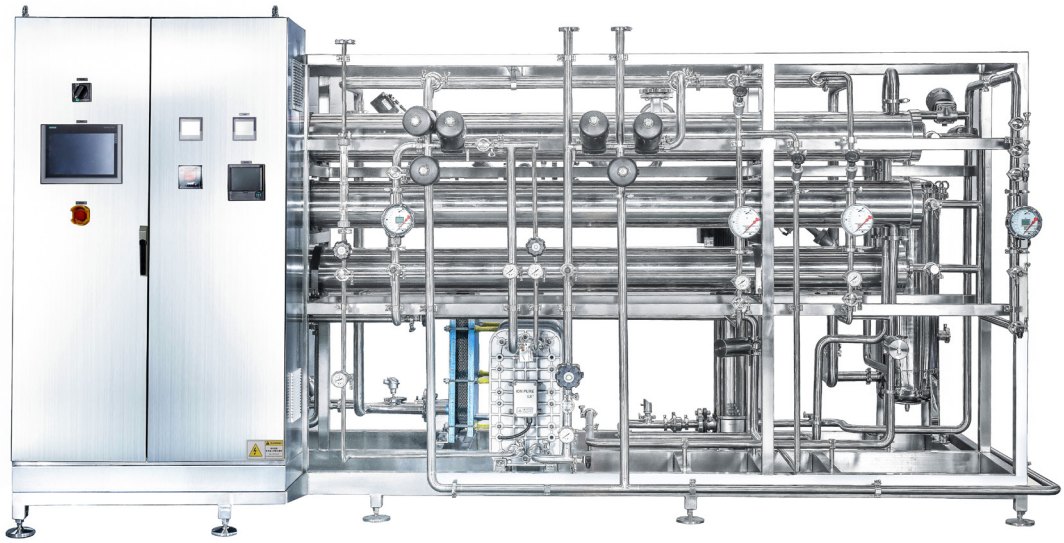
PURIFIED WATER GENERATION SYSTEM

01



Design Characteristics

Based on the raw water quality, the final water quality requirement, and the differentiated needs of customers, we will customize the purified water generation system for customers ensuring that the design meets GMP requirements and related standards.

Purified Water Generation System Includes

Filtration, softening, ultrafiltration, chemical dosing system, RO, EDI and other modules, according to the actual needs.

Our Advantages

. Process optimization, system internal circulation design, avoiding the risk of microbial growth caused by shutdown during without water consumption period, and short response time of restarting.
. Energy saving optimization: according to the customer's raw water quality, combined with process design , the water production rate is up to 80%.
. Sanitization optimization: chemical sanitization or hot water sanitization.
. Module optimization: the whole system is integrated on an independent frame, save space and time for site work.
. Automatic-control optimization: multiple operating modes as option to meet different production needs.

Quality of purified water

Purified water				
Parameter	Unit	USP	EP	CP
TOC	mg/L	0.5	0.5	0.5
Conductivity	μs/cm@ 25°C	≤1.3	≤5.1	≤5.1
Nitrate(NO3)	ppm	–	≤0.2	≤0.06
Heavy metals	ppm	–	≤0.1	≤0.1
Aerobic bacteria	CFU/ml	≤100	≤100	≤100

MULTI EFFECT WATER STILL

02

Design Characteristics

Design and manufacture according to the“GB150-1998”, “JB20030-2004”, all parts are made of 304 or 316L stainless steel.
Three stage separation ensure the high quality WFI, meets the latest USP, EP and CP2015.
Self-sterilization concept if the equipment fully meets the requirements of GMP.

Multiple-Effect Water Stills with falling film design to remove pyrogenic material. The water stills are steam heated and include a Programmable Logic Controller (PLC) for easy operation and monitoring. The quality of the generated WFI meets the latest versions of United States Pharmacopeia (USP), European Pharmacopeia (EP) and Chinese Pharmacopeia (ChP).

Quality of water for injection

Water for injection				
Parameter	Unit	USP	EP	CP
TOC	mg/L	0.5	0.5	0.5
Conductivity	μs/cm@25C	≤1.3	≤1.3	≤1.3
Nitrate(NO3)	ppm	–	≤0.2	≤0.06
Heavy metals	ppm	–	–	≤0.1
Aerobic bacteria	CFU/100ml	≤10	≤10	≤10
Bacterial endotoxins	EU/ml	≤0.25	≤0.25	≤0.25

PURE STEAM GENERATOR

03

Design Characteristics

The industrial steam is used as the heat medium, the purified water is used as the raw material water, to produce high-purity pure steam without pyrogen and it can be effectively prevented the cross contamination of the impurity materials such as heavy metals and pyrogen.

Short response time, suitable for medium and low pressure industrial steam (3-8 bar), pure steam production pressure 2-5 bar.

Pure steam quality meets non-condensable gas content, dryness, and superheat requirements as defined by HTM2010(EN285).

STORAGE AND DISTRIBUTION SYSTEM

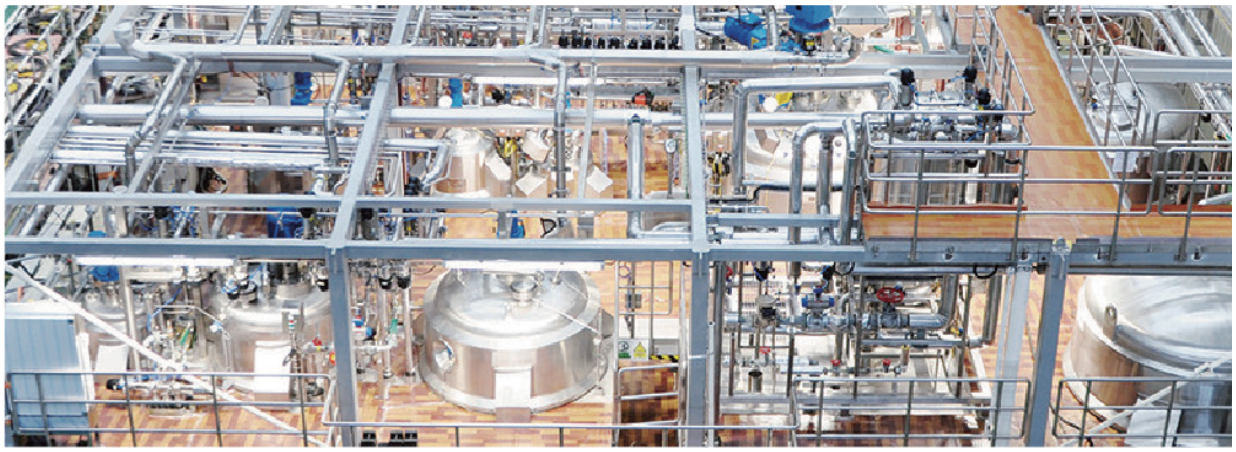
04

Design Characteristics

The water is transfered to the point of use through the storage and distribution system, including the delivery unit, the disinfection unit and automatic control unit. The above units are integrated on one frame, compacted structure to save space and easy operation and maintenance. Modular design easy for FAT and SAT.

The pipeline system provides customers with reliable purified water, water for injection, pure steam, compressed air, nitrogen, oxygen, etc. The pipeline system complies with GMP requirements, there are no blind tubes and dead leg, and the pipeline installation process passes through endoscopy, slope Instrument, welding process, etc. to ensure the quality of the pipeline, to meet the various water use, gas demand.

Quality of production water (PW/WFI) is in line with the provisions of USP, EP and CP. The design, manufacture, installation, commissioning and final acceptance of the storage and distribution system comply with the relevant requirements of GMP and FDA.



PREPARATION SYSTEM

Preparation system is widely used in liquid mixing systems for biopharmaceuticals, small volume injection products (freeze-dried, lipid microspheres, liposomes and fat emulsions), large volume parental solution (amino acids, fat emulsions), eye drops, contrast media, Chinese medicine injection and oral liquid, etc.

Design Characteristics

We provide our customers with a complete solution for the preparation system, ensuring that the entire system is sterile, with minimal residue, easy to clean and sterilize, and easy to operate and maintain. At the same time, we provide complete traceable documents in compliance with FDA, EU EMA and WHO GMP requirements.

AUTOMATIC CONTROL SYSTEM

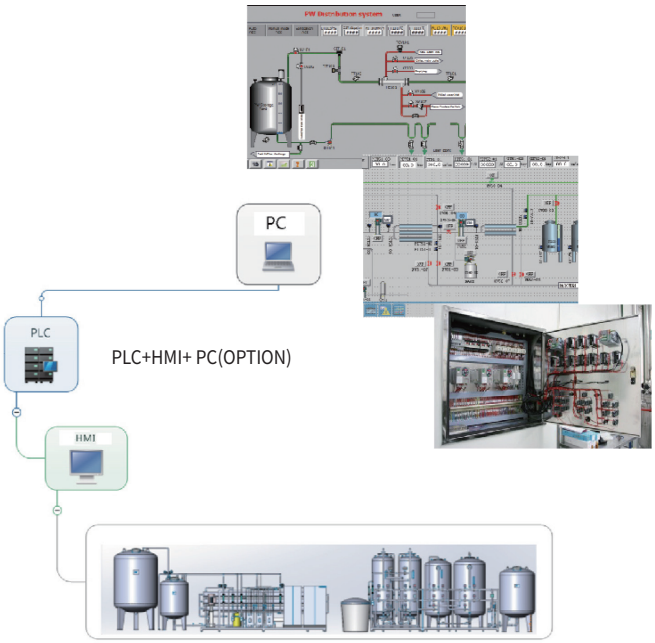
The automatic control system can be divided into setting unit, display unit, control unit, recording unit, formula unit etc., to achieve four-level password operation, electronic record/signature, in line with GMP requirements.

Advanced, stable, reliable and simple control system optimizes the effectiveness of the production process, ensures the stability of product quality, and reduces production costs.

Our team makes cost-effective automated control systems to meet the specific needs of customers.

Automatic control services include:

Electrical design, electrical installation, software programming, electronic control cabinet manufacture, FDS development, system debugging.



VALIDATION DOCUMENTS

Validation and documentation engineers accompany each project through all steps of the V-model, starting with the URS and ending with FAT, SAT/IQ, OQ, LINELINK can also support the customer in the PQ phase.

Regulations and guidance documents

- cGMP, FDA
- USP, EP, CP
- ICH (Q7, Q9, Q10)
- ISPE -Water&Steam systems-Commissioning &Qualfication
- GAMP5