

**南通海发制药设备有限公司**  
High Fine Pharmaceutical Equipment Co., Ltd  
**南通海发水处理工程有限公司**  
High Fine Engineering Ltd

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符合FDA标准的水系统设备  
全球水系统设备主流供应商

*FDA standard water system  
Mainstream supplier of global water system*



## 符合FDA标准的水系统设备

Water system equipment that meet FDA standards

## 全球水系统设备主流供应商

Main supplier of global water system equipment



# 专业

Profession  
Achievement  
Value

# 成就

# 价值



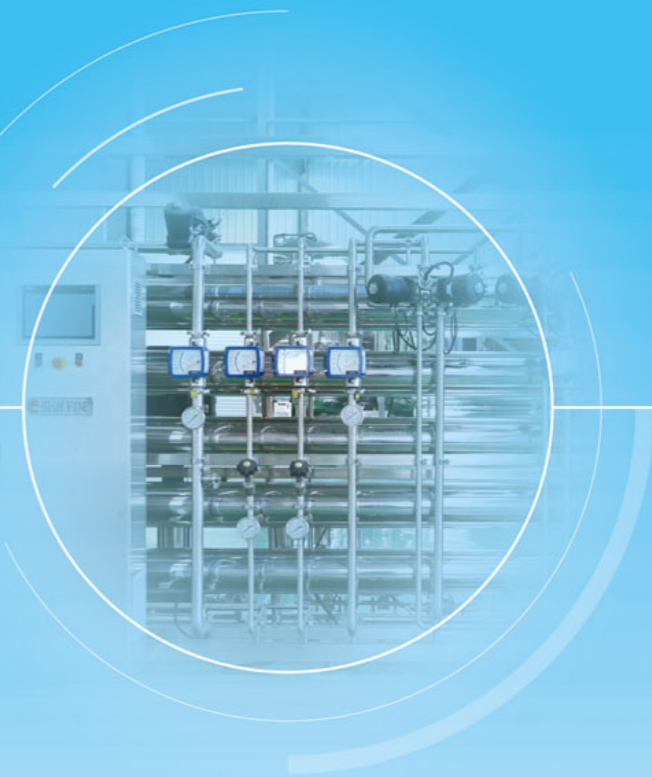
## 使命与价值观

Mission and values

**HIGHFINE** 始终以药企的经济效益、社会责任、人类健康作为我们的生存价值。愿与国内外支持和关心中国制药工业产业化事业的朋友们一起在中国这片希望的热土上，勤恳耕耘，为实现科技兴邦，造福人类的健康事业，尽己所能、奉献不息！

HIGHFINE always takes the economic benefits of pharmaceutical companies, social responsibilities and human health as our value of survival. We would like to do diligent work, to do what we can and continuous dedication of life in order to realize health undertakings that can invigorate a nation with technology and that can bring benefit to the people in Chinese hope land together with the friends who support and care about the industrialization of China pharmaceutical industry.

携手共进 **26**年  
 26 YEARS, HAND IN HAND  
 COMMON DEVELOPMENT



A collection of logos for various pharmaceutical and chemical companies, arranged in a grid-like pattern across the bottom half of the page. The logos include:

- Haier**
- 先声药业 Simcere**
- 阿胶 AEE**
- 天士力 TASYL**
- 华北制药**
- 湖南一格制药有限公司 HUANA YIGE PHARMACEUTICAL CO.,LTD**
- 东盛集团 TOPSUN GROUP**
- 佛慈制药**
- 康恩贝 CONBA**
- 南京医药股份有限公司**
- 步长制药 BUCHANG PHARMACY**
- 国药集团 SINO PHARM**
- BIOMERIEUX**
- 新华**
- 康恩贝 CONBA**
- 佛慈制药**
- 达因药业**
- SPH 上药集团**
- CTTC**
- 悦康药业集团有限公司 YOUKARE PHARMACEUTICAL GROUP CO.,LTD**
- 东北制药 NORTHEAST PHARM**
- 华东医药 HUADONG MEDICINE**
- 海王医药**
- 汉森制药 Hansen Pharm.**
- 华邦制药 HUAPONT PHARM**
- 华仁堂**
- 云药集团 YUNTAO GROUP**
- NUTRICIA 纽迪希亚**
- 长澳药业 C&O**
- 健康元 Joincare**
- 普洛 APELOA 普洛**
- 常州千红生化制药股份有限公司 Changzhou Qianhong Bio-pharma Co.,Ltd.**
- 现代制药 SHYNDEC**
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- 二叶制药 ERYE 二叶制药**
- 中新药业 zhongxin pharmaceuticals**
- 康哲药业控股有限公司 CHINA MEDICAL SYSTEM HOLDINGS LTD. CHINA MEDICAL SYSTEM HOLDINGS LTD.**
- 扬子江药业集团**
- 白敬宇制药 BAIJINGYU PHARMACEUTICAL**
- 同联集团 TONGLIAN 同联集团**
- Bayer MaterialScience**
- FOSUNPHARMA 复星医药**
- 河南新乡华星药厂 Henan Xinxiang Hua Xing Pharmaceutical Factory**
- 聚光古汉集团股份有限公司 UNSPLENDOR GUHAN GROUP CORPORATION LIMITED**
- 同仁堂**
- 同仁堂**
- 同仁堂**

## 主要为国内外制药企业提供：

HIGHFINE mainly provides the following equipments for domestic and foreign main pharmaceutical enterprises:

Design, installation and verification of pharmaceutical water preparation units  
制药用水制备机组的设计、安装和验证

RO EDI纯化水制备机组  
RO EDI purified water preparation unit

S系列多效蒸馏水机  
S series multi-effect water distiller

F系列多效蒸馏水机  
F series multi-effect water distiller

B系列多效蒸馏水机  
B series multi-effect water distiller

F/S系列纯蒸汽发生器  
F/S clean steam generator

Design, installation and verification of distribution unit  
分配机组的设计、安装和验证

PW纯化水分配机组  
PW purified water distribution unit

WFI注射用水分配机组  
WFI water for injection distribution unit

Design, manufacturing and installation of mixing liquid tank and liquid conveying system  
配料罐及配料系统设计、制造和安装

发酵罐系统  
Fermentation tank system

CIP SIP系统  
CIP SIP systems

## 关于海发 About us

HIGHFINE 是国内唯一的专业生产制药用水设备的合资企业。公司采用欧美技术将世界领先的制造技术引进中国，为制药企业提供完全符合欧美药典FDA要求的水系统设备，拥有国际权威的制药用水设备专业工程师。从而保证每套设备的设计、制造、工程施工、验证服务和售后服务的质量。

HIGHFINE 不但是中国制药工业水系统设备的主流供应商。我们的奋斗目标和最终的理想：要成为全球制药工业水系统设备的领军者和主流供应商。

High Fine is the only joint venture in China to manufacture pharmaceutical water equipments professionally. The Company adopts the European and American technologies to introduce the world leading manufacturing technology into China and to provide water system equipment that completely meet the requirements of European and American pharmacopoeia. In addition, the Company has international authoritative engineers in pharmaceutical water equipment field. Under this circumstance, the design of each set of equipment, the equipment manufacturing, construction, the quality of authentication service and after-sale service are assured.

HIGHFINE is not only the mainstream supplier of the water system equipments in Chinese pharmaceutical industry. Our struggle objective and the ultimate ideal are to become the leader and mainstream supplier of the water system equipments in global pharmaceutical industry.

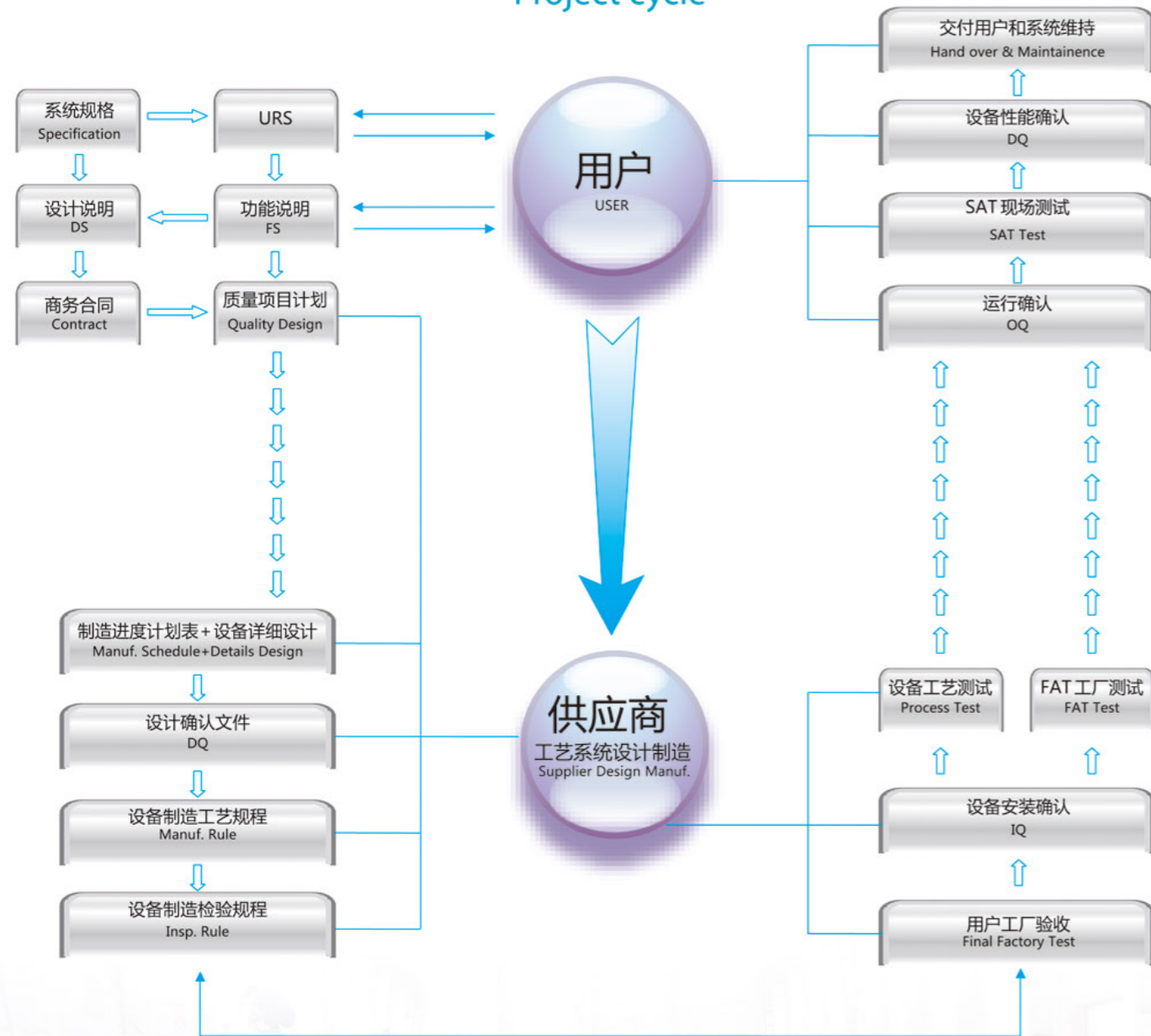
寸金的光阴堆积起来的26年，转眼即逝。我们从年青走向了成熟，从过去的满怀热情变成了今天的更执着、更严谨，因为我们深深的感受到责任重于泰山。

时间把我们的理想变得具体，赋予了它真正的意义。如果由于我们的努力，使人类的生存环境得到了更好的改善，那我们将感到，海发人的智慧是无穷的。

Time passed quickly. We from young to mature, from full of enthusiasm in the past into today's more persistent and more rigorous, because we deeply feel that the responsibility be weightier than Mount Tai. Time made our ideal specific, given its true meaning. If human's living environment better improved as our efforts, then we will feel that HighFine's wisdom is infinite.

# 项目周期

Project cycle



# 工程设计咨询&管理验证

Engineering design consulting and management verification



简单地验证的职责由开发商（设计），质量保证部门（检测）和使用者（操作）三方面承担。开发商的职责是系统的开发及技术支持，文件的编写与必要的测试，质量保证部门的职责是建立验证方针及验证步骤。

一个正确的被检验过的工艺可以连续地生产出具有高纯度和安全性的产品，并符合预计成本及额定产量，从而降低成本，保证质量，符合GMP规范和FDA要求。

Simply speaking, the responsibility of validation is assumed by developer (design), quality assurance department (certify) and users (operate). The responsibility of developer is providing system development and technology support, compiling and making necessary test for documents. While the quality assurance department is responsible for constituting validation guideline and steps.

A process which is correct and had been verified can sequentially produce products which meet with intending cost and quality and are of high purity and safety. Then they can reduce cost, guarantee quality and comply with GMP specification and FDA requirement.

本公司可提供的验证咨询服务包括：

- 制定验证总计划
- 编写验证方案
- \*设计认证 (DQ)      \*安装认证 (IQ)
- \*校验 (Calibration)      \*运行确认 (OQ)
- \*性能认证 (PQ)
- 计算机系统验证
- 编写标准程序 (SOP)
- 培训

Our company provide following validation consulting service:

- establishing validation master plan
- compiling validation scheme
- \*Design qualification (DQ)      \*Installation qualification (IQ)
- \*Calibration      \*Operation qualification (OQ)
- \*Performance qualification (PQ)
- Computer system validation
- Compiling standard operation procedure (SOP)
- Training

# 硬件设备保障

Hardware devices

## 精细管理

每一个微小的细节都值得我们密切关注，每一个细小的行动都是 **HIGHFINE** 员工工作中的有机组成部分。只有对它给予足够的关注，修正细小的偏差，企业才能成就宏图伟业。**HIGHFINE** 以此为标准，不断提高自己以做到完美为己任。

## Fine Management

Every tiny detail is worthy of our close attention, every small action is the part which HighFine's staff working in. Only to give enough attention, correct tiny deviation, can the enterprise achieve success. HighFine based on this standard, and constantly strive to improve ourselves to be perfect as our duty.



自动纵缝焊机

Automatic longitudinal seam welding machine



自动环缝焊机

Automatic circumferential seam welding machine



管板自动焊机

Tube plate automatic welding machine



Orbitalum GF4切管机

ORBITALUM GF4 pipe cutting machine



自动轨迹焊

Automatic track welding



激光切割机

Laser cutting machine



数控龙门镗铣床

Gantry CNC boring and milling machine

## 精益生产

**HIGHFINE** 的精益生产管理体系由成本定额控制体系，作业工时定额管理体系、工艺菜单体系、6S现场作业管理体系四大部分组成。

通过对生产制造过程中所耗用的物料、能源、人工工时、工艺设计、现场管理要求等的严格管控，实现以成本最低化、效益最大化为目标的自创精益生产管理体系。

## Lean production

HighFine's lean production management system includes 4 parts. They are the cost quota control system, the work hours quota management system, process menu system, 6s on-site management system.

Through strict control in the production process of consumption of materials, energy, artificial time, process design, site management requirements, to realize the target: the lean production management system with minimization of cost and benefit maximization.

# 专业、安全、标准

Specialization, Securitization, Standardization

## 独有“3S”品质控制体系

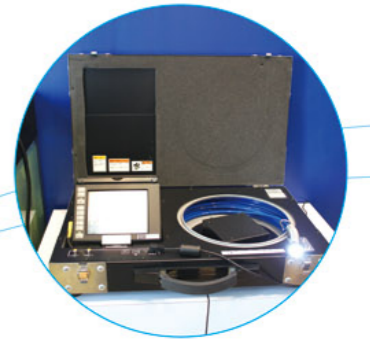
**HIGHFINE** QC检测中心  
为每一件产品提供高效可靠的检测与质量控制  
确保每道工序均满足用户的要求  
为使客户满意，我们倾尽全力

## The unique "3S" quality control system

HighFine QC testing center.  
To provide efficient reliable testing and quality control for each product.  
To ensure that each procedure to meet the requirements of customers.  
We do our best to make customers' satisfaction.

## 内窥镜检测仪

Endoscopic detector



## 测厚仪

Thickness tester



## 粗糙度检测仪

Roughness tester



## X光探伤仪

x-ray detector



## 不锈钢元素分析仪

Stainless steel element analyzer



► 纯化水系统

我们对纯化水系统的设计以模块化设计为理念，使纯化水系统具有独立化，模块化、操作简易化的特点，保证了设备运行的连续性、稳定性、可靠性。并根据客户提供的水质报告和URS，作出两种以上的设计方案供客户选择。包括预处理的配置、脱盐系统的组合、分配系统的选择、消毒方式等等。同时我们还为客户提供一套完整的验证系统包括前期的设计确认、厂内的FAT测试、后期安装确认、运行确认和性能确认以及完善的售后服务体系。

► Purified water system

We take modular design as the concept for the purified water system design to make the purified water system has such characteristics of independence, modularization and simple operation, etc, which endures the consecutiveness, stability and reliability of equipment operation. In addition, we will make more than two design plans for the selection by the clients in accordance with the water quality report and URS provided by the clients, including pretreatment configuration, combination of desalination system, selection of distribution system and disinfection methods, etc. In the meantime, we also provide a complete set of verification system for clients, including design validation in the preliminary stage, FAT test within the factory, installation validation in later stage, operation validation and performance validation as well as perfect after-service system.

► 纯蒸汽发生器

纯蒸汽通常是以纯化水为原料水，通过纯蒸汽发生器或多效蒸馏水机的第一效蒸发器所制备的蒸汽，纯蒸汽冷凝时要满足注射用水的要求。去离子水和纯化水都可作为纯蒸汽发生器的原料水，经蒸发、分离（去除微粒及细菌内毒素等污染物）后，在一定压力下输送到使用点。

► Clean steam generator

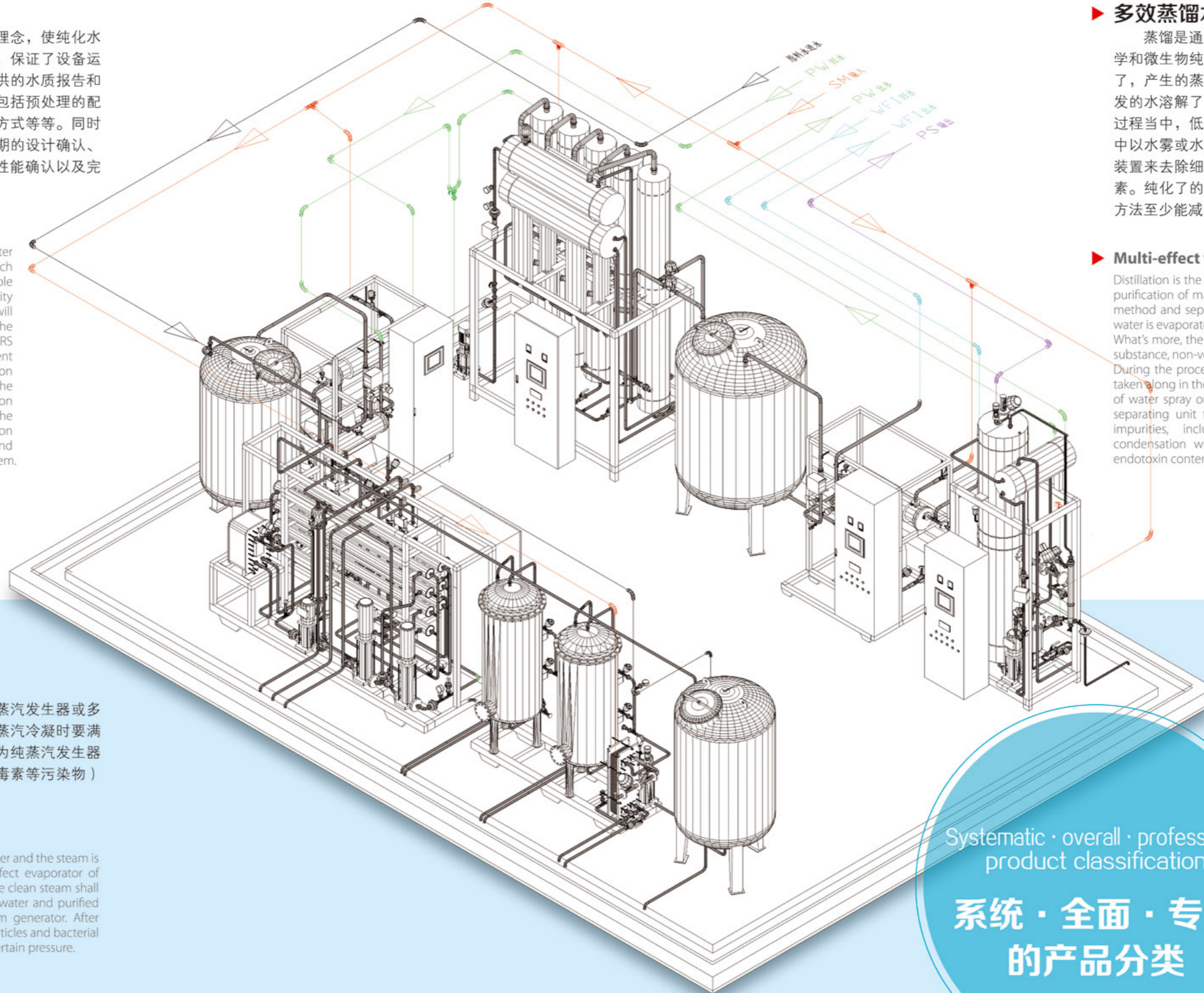
The clean steam usually takes purified water as feeding water and the steam is produced through pure steam generator or the first effect evaporator of multi-effect water distiller. At the time of condensation, the clean steam shall meet the requirements of water for injection. Deionized water and purified water can all be taken as feeding water of clean steam generator. After evaporation and separation (remove such pollutants as particles and bacterial endotoxin), it can be conveyed to the using point under certain pressure.

► 多效蒸馏水机

蒸馏是通过气液相变法和分离法来对原料水进行化学和微生物纯化的工艺过程。在这个工艺当中水被蒸发了，产生的蒸汽从水中脱离出来，而流到后面去的未蒸发的水溶解了固体、不挥发物质和高分子杂质。在蒸馏过程当中，低分子杂质可能被夹带在被水蒸发后的蒸汽中以水雾或水滴的形式被携带，所以需要通过一个分离装置来去除细小的水雾和夹带的杂质，这其中包括内毒素。纯化了的蒸汽经冷凝后成为注射用水。通过蒸馏的方法至少能减少99.99%内毒素含量。

► Multi-effect water distiller

Distillation is the technical process for chemical and microbiological purification of material water through steam-liquid phase transition method and separation method. During this technical process, the water is evaporated and the steam produced isolated from the water. What's more, the unevaporated water that flow back dissolved solid substance, non-volatile matter and high molecular weight impurities. During the process of distillation, low molecular impurities may be taken along in the steam produced by water evaporation in the form of water spray or water drop. Under this circumstance, we need a separating unit to remove the thin water spray and the carried impurities, including endotoxin. The purified steam after condensation will become water for injection. At least 99.99% endotoxin content may decrease through distillation method.



Systematic · overall · professional  
product classification

系统 · 全面 · 专业  
的产品分类

## 水系统设备 RO系统

Water system equipment / RO system

### ► 应用范围:

电子、医药、食品等工业中纯水；轻纺、化工用水的净化和制备；食品饮料用水、酿酒工艺用水的净化与制备；工业生产中在水溶液进行有用物质和浓缩与回收；电厂等企业高压锅炉补给水的预脱盐处理；苦咸水和海水的脱盐淡化；作为高纯水生产的一级除盐设备。

### ► Scope of application:

Pure water in such industries as electronics, medicine and food, etc; purification and preparation for water used in textile industry and chemical industry; purification and preparation for water used in food and drinks and enological process; concentration and recovery of the useful materials of aqueous solution in industrial production; preliminary desalination processing of high pressure boiler make-up water of the enterprises, such as electrical power plant, etc.; brackish water and seawater desalination; as the first class desalinating equipment for high purity water production.



## 水系统设备 RO+EDI系统

Water system equipment / RO + EDI system

EDI装置属于精处理水系统，一般多与反渗透（RO）配合使用，组成预处理、反渗透、EDI装置的超纯水处理系统，取代了传统水处理工艺的混合离子交换设备。EDI装置进水要求为电阻率为0.025-0.5MΩ·cm，反渗透装置完全可以满足要求。EDI装置可生产电阻率高达15MΩ·cm以上的超纯水。

EDI equipment belongs to fine treatment water system and usually used in cooperation with reverse osmosis (RO) to constitute the ultrapure water treatment system with pretreatment, reverse osmosis and EDI devices. EDI equipment replaced the mixed ion-exchange unit used in traditional water treatment technology. EDI equipment requires the electrical resistivity of the water to reach 0.025-0.5MΩ·cm and the reverse osmosis device can completely meet the requirements. EDI equipment can produce ultrapure water with the electrical resistivity above 15MΩ·cm.





## 水系统设备 热水消毒的纯化水设备

Water system equipment  
Hot water disinfection purification water system

### ▶ 纯水设备要求:

- 水质符合中国药典标准和FDA中各项规定;
- 设备全自动运行和有条件的全自动处理程序 (如反冲洗、再生、酸洗、消毒程序);
- 单体和管道设备符合GMP的要求 (如后端处理设备杀菌器、膜滤、终端水箱、管路均采用316L材料, 预处理设备的管路采用SUS304材料)。

### ▶ Pure water equipment requirements:

- The water quality meets all the provisions of China pharmacopoeia standard and FDA;
- Automatic equipment operation and conditional automatic processing program (such as back flush, regeneration, acid-washing and disinfection procedures);
- Monomer and pipe equipment meet GMP requirements (all such back end processing equipments as sterilizer, membrane filtration, terminal water tank and pipeline adopt the 316L material and the pre-treatment pipeline adopts SUS304 material).



## 水系统设备 二级RO+EDI纯化水系统

Water system equipment / Second class RO+EDI purified water system

### ▶ 纯水水质标准:

- 电导率 $\leq 0.5\mu\text{s}/\text{cm}$
- $\text{TOC} \leq 200\text{ppb}$
- 微生物 $\leq 20\text{cfu}/\text{ml}$

### ▶ Pure water quality standards:

- Electrical conductivity:  $\leq 0.5\mu\text{s}/\text{cm}$
- $\text{TOC} \leq 200\text{ppb}$
- Microorganism  $\leq 20\text{cfu}/\text{ml}$



## 多效蒸馏水机设备 S型蒸馏水机

Multi-effect water distiller  
S series multi-effect water distiller

S系列多效蒸馏水机基于降膜和多级蒸发原理设计而成的，第一效由外部热源加热（工业蒸汽），随后各柱都使用前效产生的纯蒸汽得到足够的热能。第一效没有蒸发的原料水做下一效的原料水，以此类推。

S series multi-effect water distiller is designed according to the principle of falling film and multiple-stage evaporation. The first effect is to conduct heating by external heat source (industrial steam) and then each pillar can get enough heat energy by using the pure vapor produced from the fore-effect. The material water that did not evaporated in the first effect can be taken as the material in the next effect and so on.

### ▶ 设备特点:

- 整个设备采用316L不锈钢制成，工作表面经过酸洗和钝化处理。
- 管道系统采用镜面抛光0.6μmRa的316L不锈钢管，自动轨迹焊接，洁净法兰和制药级的垫圈连接。
- 保温采用岩棉，外覆304不锈钢亚光处理保护层，架体为不锈钢。

### ▶ Equipment features:

- The whole equipment is made by 316L stainless steel and the operation surface is conducted with acid-washing and passivating treatment;
- The pipeline system adopts the mirror polish 0.6μmRa 316L stainless steel tube and conducts with automatic track welding and connects with clean flange and pharmaceutical level gasket.
- Use material wool to keep warm and the exterior of the equipment is covered with 314 stainless steel matte finishing protective layer and its scaffold is made of stainless steel.



## 多效蒸馏水机设备 S型蒸馏水机技术参数

Multi-effect water distiller  
Technical parameters of S series multi-effect water distiller

工业蒸汽进气工作压力: 0.3MPa, 冷却水进水工作压力: 0.2MPa

Inlet pressure of industrial steam is 0.3MPa and the inflow working pressure of cooling water is 0.2MPa

规格型号 Product model	效数 Number of effect	生产能力 Lt/h Production capacity	原料水 Kg/h Material water	工业蒸汽 Kg/h Industrial steam	冷却水 Lt/h Cooling water	高 mm Height	长 mm Length	宽 mm Width
MS100	4	100	115	45	80	2650	1300	710
MS200	4	200	230	76	120	2650	1360	710
MS200	5	200	230	62	50	2650	1620	710
MS300	4	300	345	109	190	2650	1410	730
MS300	5	300	345	89	90	2650	1730	730
MS500	4	500	575	185	310	3170	1680	900
MS500	5	500	575	148	130	3170	2000	900
MS750	4	750	865	256	300	3260	1680	900
MS750	5	750	865	205	178	3260	2000	900
MS1000	5	1000	1150	295	256	3685	2180	980
MS1000	6	1000	1150	245	65	3685	2830	980
MS1500	5	1500	1725	460	390	3685	2680	1100
MS1500	6	1500	1725	380	95	3685	3150	1100
MS2000	5	2000	2300	540	345	3940	3150	1100
MS2000	6	2000	2300	490	130	3950	3580	1100
MS3000	6	3000	3450	730	190	4050	4000	1200
MS4000	6	4000	3450	910	310	4800	4000	1200
MS5000	6	5000	5750	1140	440	4200	4550	1350

## 多效蒸馏水机设备 F型蒸馏水机

Multi-effect water distiller  
F series multi-effect water distiller

F系列多效蒸馏水机采用三级离心分离技术，西门子S7系列控制系统，带有中英文操作语言，标准配置的进水升压泵，带有缓冲、收集筒。标准配置工厂蒸汽减压阀，连续排放不凝气体装置，连续进行残液排放，对注射用水电导率和阀门位置进行记录，完整的设备制造工厂验收测试(FAT)，进水采用去离子水或RO水。

F series multi-effect water distiller adopts Level 3 centrifugal separation technology. Siemens S7 series control system has Chinese and English operating language, water inlet booster pump with standard configuration, dashpot and collection tank. The equipment is equipped standard with plant steam reducing valve, the device for continuous emission of non-condensable gas. In addition, the F series equipment continuously discharge the residual liquid and record the electrical conductivity of water for injection and the valve location. It is conducted with complete equipment manufacture factory acceptance test and the inlet water uses deionized water or RO water.



## 多效蒸馏水机设备 F型蒸馏水机技术参数

Multi-effect water distiller  
Technical parameters of F series multi-effect water distiller

工业蒸汽进气工作压力：0.3MPa, 冷却水进水工作压力：0.2MPa

Inlet pressure of industrial steam is 0.3MPa and the inflow working pressure of cooling water is 0.2MPa

规格型号 Product model	效数 Number of effect	生产能力 Lt/h Production capacity	原料水 Kg/h Material water	工业蒸汽 Kg/h Industrial steam	冷却水 Lt/h Cooling water	高 mm Height	长 mm Length	宽 mm Width
MS100	4	110	127	38	70	2310	1420	1110
MS200	4	220	253	75	138	2310	1520	1110
MS200	5	220	253	56	60	2310	1770	1110
MS300	4	330	365	110	220	1310	1520	1110
MS300	5	330	365	90	102	2310	1770	1110
MS500	4	550	630	180	350	2850	1610	1290
MS500	5	550	630	145	170	2850	1910	1290
MS750	4	770	860	254	485	3380	1810	1390
MS750	5	770	860	203	225	3380	2160	1390
MS1000	5	1100	1265	290	310	4100	2850	900
MS1000	6	1100	1265	245	70	4100	3330	900
MS1500	5	1600	1810	415	460	4200	3190	1000
MS1500	6	1600	1810	350	130	4200	3700	1000
MS2000	5	2200	2510	568	640	4300	3600	1200
MS2000	6	2200	2510	475	176	4300	4200	1200
MS3000	6	3300	3700	720	270	4450	4510	1200
MS4000	6	4300	4945	930	360	4800	4510	1200
MS5000	6	5500	6225	1185	470	5500	6040	1380

## 多效蒸馏水机设备 B型蒸馏水机

Multi-effect water distiller  
B series multi-effect water distiller

B系列多效蒸馏水机采用升膜多导流形式蒸发，工业蒸汽经阀门进入蒸发器壳程，与管程的纯化水升膜热交换，热交换后的纯化水形成蒸汽，经交换后的纯化水形成蒸汽，经设备内多导流分离装置将蒸汽中的杂质热源去除，形成二次蒸汽。经汽水分离的纯汽再给II效做加热源冷凝后即为蒸馏水在压差的作用下进入冷凝器，通过管道进入储罐储存。没有蒸发和分离的浓水经浓水出口进入下一次再次蒸发。

B series multi-effect water distiller adopts rising film and multi-diversion form to evaporate. The industrial steam enters the evaporator shell pass through valves and interchange heat with the purified water rising film in tube pass. The purified water after heat exchange becomes vapour, then impure heat source will be removed from the vapour through diversion separation device in the machine to produce the secondary steam. The pure steam after steam-water separation will become distilled water after being condensed as heating source in II effect. Then the distilled water will enter into the condenser under the pressure differential action and then enter the storage tank through the pipe for storage. The concentrated water without evaporation and separation shall enter the next effect for re-evaporation through concentrated water inlet.

### ▶ 设备特点:

- 采用升膜蒸发，解决布水不均匀问题。
- 换热效率高，100%换热。
- 节省工业蒸汽耗量，节能20%。
- 精确分配每一效原料水用量，减少原料水损耗。
- 多导流分离装置无需更换，设备使用寿命延长。

### ▶ Equipment features:

- Adopts rising film for evaporation to solve the problem of uneven distribution of water.
- High thermal efficiency, 100% heat exchange.
- Save industrial steam consumption, 20% energy saving.
- Distribute feeding water consumption amount for each effect accurately to reduce material water loss.
- No need to exchange the multi-diversion separation device and life-span of the equipment can be extended.



## 多效蒸馏水机设备 B型蒸馏水机技术参数

Multi-effect water distiller  
Technical parameters of B series multi-effect water distiller

工业蒸汽进气工作压力: 0.3MPa, 冷却水进水工作压力: 0.2MPa

Inlet pressure of industrial steam is 0.3MPa and the inflow working pressure of cooling water is 0.2MPa

规格型号 Product model	效数 Number of effect	生产能力 Lt/h Production capacity	原料水 Kg/h Material water	工业蒸汽 Kg/h Industrial steam	冷却水 Lt/h Cooling water	高 mm Height	长 mm Length	宽 mm Width
MS100	4	120	132	35	101	2500	1400	800
MS200	4	220	242	54	80	2600	1600	900
MS200	5	220	231	50	40	2600	1800	900
MS300	4	330	365	78	120	2700	1700	900
MS300	5	330	358	65	60	2700	1990	900
MS500	4	515	540	157	230	2900	1700	900
MS500	5	507	522	123	90	2900	1990	900
MS750	4	760	800	243	240	3100	1700	1100
MS750	5	750	780	196	100	3100	2100	1100
MS1000	5	1015	1045	247	150	2900	3100	1200
MS1000	6	1000	1030	203	30	3100	3500	1200
MS1500	5	1522	1568	370	240	3100	3500	1300
MS1500	6	1500	1545	304	60	3100	4000	1300
MS2000	5	2029	2090	493	190	3300	4100	1400
MS2000	6	2000	2060	406	100	3600	5000	1500
MS3000	6	3000	3090	609	140	3800	5100	1500
MS4000	6	4000	4120	812	160	4200	5400	1500
MS5000	6	5000	5200	1015	240	4500	6150	1600

# 纯蒸汽发生器

## Clean Steam Generator

### ▶ 生产能力:

标准设备型号表显示的是在纯蒸汽压力为3bar,工业蒸汽为6bar的情况下的设备生产能力,单位是公斤/小时。如果要获得某种型号设备的实际生产能力,则必须根据实际工作压力,在标定生产能力上乘上一个转换系数。

### ▶ Production capacity

The standard equipment model table shows the equipment production capacity under the condition of 3bar pure steam pressure and 6bar industrial steam with the unit in kg/h. The actual production capacity of some type equipments shall be acquired in accordance with the actual operation pressure and use this actual operation pressure to multiply the conversion coefficient in the specified production capacity.

### ▶ 型号选择举例:

- 工业蒸汽压力: 7bar
- 所需纯蒸汽压力: 2bar
- 纯蒸汽最高需求量: 500公斤/小时
- 转换系数: 1.7
- 标定输出需求:  $500/1.7=294$ 公斤/小时
- 选择型号: PSG300DTS

### ▶ Model selection example

- Industrial steam pressure: 7bar
- Pure steam pressure needed: 2bar
- The highest demand of pure steam: 500kg/h
- Conversion coefficient: 1.7
- Specified output needs:  $500/1.7=294$ kg/h
- Model selected: PSG 300 DTS



### ▶ 公用工程需求:

- 不含杂质和腐蚀性物质的工业饱和蒸汽; 最大压力为9bar
- 进料水要求为去离子水, 无硅石, 氯, 胺, 挥发性物质等等, 压力要求为1-2bar
- 供电标准: 根据客户要求。
- 干燥、无油、干净的压缩空气, 最小压力要求为6bar

### ▶ Public facility demand

- Industrial saturated steam without impurities and corrosive materials, the maximum pressure is 9bar.
- Feeding water requires deionized water without silica, chlorine, amine and volatile substance, etc. The pressure required is 1-2bar.
- Power supply standards: according to the clients' requirements.
- Dry, oil-free and clean compressed air, the minimum pressure required is 6bar.

# 纯蒸汽发生器 技术参数

## Technical parameters of Clean Steam Generator

工业蒸汽进气工作压力: 0.3MPa, 纯蒸汽工作压力: 0.15-0.2MPa

Inlet pressure of industrial steam is 0.3MPa and the pure steam working pressure is 0.2MPa

规格型号 Product model	生产能力 Lt/h Production capacity	原料水 Kg/h Material water	工业蒸汽 Kg/h Industrial steam	高 mm Height	长 mm Length	宽 mm Width
PSG100	100	115	130	2100	900	570
PSG200	200	230	250	2500	900	570
PSG300	300	345	370	2500	1110	680
PSG400	400	460	480	2600	1110	680
PSG500	500	575	173	2600	1170	720
PSG800	800	920	960	3500	1775	930
PSG1000	1000	1150	1200	3700	1775	930
PSG2000	2000	2300	2400	4000	2030	1900
PSG3000	3000	3450	3600	4850	2030	1900
PSG4000	4000	4600	4800	5100	2200	2100

## 贮存分配系统 纯水贮存分配系统

Storage distribution system  
Pure water storage distribution system

根据客户现场实际需求及消毒的要求定制设计，以GMP、ISPE工程指南和FDA的规范为设计理念基础，框架结构，节省空间，即插即用，安装方便，在制造工厂进行预安装与运行确认，所有管道为316L不锈钢、无死角、卫生型卡盘连接方式所有产品接触的表面，粗糙度（Ra）小于 $0.6\mu\text{m}$ ，回路中没有中间贮罐，避免细菌滋生，符合FDA要求。

Distribution system is specially designed according to customers' real situation on the basis of GMP, ISPE and FDA guidelines. The system adopts the frame structure and has such advantages as space-saving, plug-and-play and convenient installation. It will be conducted with pre-installation and operational qualification at the manufacturing plant. All the pipelines use the 316L stainless steel without dead leg and the sanitary type chuck connection mode. The roughness of the surface contacted by all products shall be less than  $0.6\mu\text{m}$ . There is no buffering tank in the loop to avoid bacteria growth, which is in compliance with FDA requirements.



## 贮存分配系统 蒸馏水贮存分配系统

Storage distribution system  
Distilled water storage distribution system

本公司WFI分配系统以GMP、ISPE工程指南和FDA的规范为设计理念基础。根据客户现场实际需求定制最优化设计。所有管道为316L不锈钢、无死角、卫生型卡盘连接方式，所有产品接触的表面，粗糙度（Ra）小于 $0.6\mu\text{m}$ ，所有管件选用ASME—BPE2000标准的配件，可实现全自动恒温控制，与蒸馏水机连机动作。所用控制阀门为进口元件，整套系统在制造工厂进行预安装与运行确认，提供全面的验证文件。

Distribution system is specially designed according to customers' real situation on the basis of GMP, ISPE and FDA guidelines. All the pipelines use the 316L stainless steel without dead leg and sanitary type chuck connection mode. The roughness of the surface contacted by all products shall be less than  $0.6\mu\text{m}$ . All the pipe fittings choose ASME-BPE2000 type accessories, which can realize thermostatic control automatically and operate with the water distiller in chain. All the control valves are imported. The whole system can be conducted with the pre-installation and operational qualification at the manufacturing plant and the comprehensive validation documents are provided.



## 在线清洗系统 固定式CIP工作站

On-line cleaning system  
Stationary CIP workstation

CIP清洗装置即可作为不分解生产设备，又可用于手动操作、自动操作的清洗系统，几乎被引进到所有的食品，饮料及制药等工厂。CIP清洗装置不仅能清洗机器，而且还能控制微生物的清洗方法。

CIP cleaning device can be used as the indissoluble production equipment and can also be used in the cleaning system with manual operation and automatic operation. The device is nearly used in such plants as food, drinks and pharmacy, etc. CIP device can not only clean the machine, but can also control the cleaning methods of microorganism.



## 在线清洗系统 移动式CIP工作站

On-line cleaning system  
Mobile CIP workstation

CIP清洗装置其有以下的优点：

- 能使生产计划合理化及提高生产能力。
- 与手洗相比较，不但没有因作业者之差异而影响清洗效果，还能提高其产品质量。
- 能防止清洗作业中的危险，节省劳动力。
- 可节省清洗剂、蒸汽、水及生产成本。
- 能增加机器部件的使用年限。
- CIP清洗装置分手动、半自动及全自动三种供用户选择。

CIP cleaning device has the following advantages:

- Can make the production plan reasonable and improve the production capacity.
- Compared with hand cleaning, CIP does not affect the cleaning effect due to different operators, but can also improve product quality.
- Can avoid the danger in the cleaning operation and save labor force.
- Can save the cost of cleaning agent, steam, water and production.
- Can increase the service life of machine components.
- CIP cleaning devices include such three types as manual operation, semi-automatic and automatic for the selection by the users.



## 配料系统生物制品用罐设备

### Biological products tank equipment in batching system

具有制造不锈钢压力容器的自动焊接设备。

具有三种处理不锈钢容器表面的工艺：

- 400#电解抛光二RaO.4 $\mu$ m；400#+600#+800#+2电解抛光二RaO.28 $\mu$ m
- 表面喷砂和表面亚光砂光Ra $\leq$ 0.6
- 电解抛光工艺和设施

Automatic welding equipment that can manufacture stainless steel pressure vessel.

Three kinds of technologies for surface treatment of the stainless steel container:

- 400#+ electrobrightening RaO. 4 $\mu$ m; 400#+600#+800#+2 electrobrightening RaO. 28 $\mu$ m
- Surface sandblasting and surface matte sanding Ra $\leq$ 0.6
- Electrolytic polishing technologies and devices

具有制造机械搅拌的车间和设备。

具有材料的理化分析，厚度检验及内表面粗糙度测试的仪器。设备设计制造完全符合FDA要求；压力容器满足国家相关标准及锅炉压力容器安全检查《固容规》要求；符合设备安装的相关标准。



Workshop and equipment for mechanical mixing.

Possess the devices for physical and chemical analysis of materials, thickness inspection and inner surface roughness test. The equipment design and manufacturing are totally in compliance with FDA requirements; the pressure vessel meets the national relevant standards and the requirements for pressure vessel safety inspection; meet the relevant requirements for equipment installation.

## 发酵罐系统

### Fermentation tank system

HF系列生物反应器是通风机械搅拌式反应器，采用PLC+彩色触摸屏系统智能控制，可满足从实验室到中试及生产规模使用。该系统具有结构简单、操作方便、自动化程度高等优点。广泛用于食用菌、药用菌液体制种，生物制药，食品添加剂，生物采油，生物能源，生物农药，生物肥料，生物饲料酶制剂、维生素等领域。

- 控制参数主要包括：温度、转速、通气量、罐压、pH、Do、补料、消泡、生物量、称重等。
- 容积：5L~500m<sup>3</sup>

HF series bioreactor is the ventilating machine stirred tank reactor and adopts PLC + color touch screen system intelligent control, which can meet the requirements for usage from the lab to pilot plant test and scale of production. This system has such advantages as simple structure, convenient operation and high degree of automation. It is widely used in such fields as edible mushroom, medicinal fungus liquid seeding, biological pharmacy, food additives, organism oil-recovery, biological energy source, biopesticide, bio-fertilizer, biological feed enzyme preparation and vitamin, etc.

- The control parameters mainly include: temperature, rotating speed, ventilatory capacity, tank pressure, pH, Do, feed supplement, defoaming, biomass liveweight and scaling, etc.
- Volume: 5L ~500m<sup>3</sup>





# 我们的产品获得众多国家及专业领域的认可

Our products obtain approval of professional field.



# 我们的优势

Our advantages

- 具有全球制药用水系统的设计、制造和工程经验
- 具有世界一流的工程技术团队
- 具有为国内国际数百家知名客户提供服务的经验
- 完全熟悉并掌握国际“药品质量管理生产规范”和行业指南以及制药行业标准
- 提供整套符合FDA、cGMP要求的文件系统
- 提供整机FAT测试文件
- 与国际主流研究领域交流和合作/与国际同步时刻掌握尖端内在的技术含量



- Have the design, manufacturing and engineering experience of global pharmaceutical water system
- Have the world first class engineering technology team
- Have the experience for providing services for more than 100 famous clients at home and aboard
- Completely familiar with and grasp the international "Good Manufacturing Practice" and industry guidelines and pharmaceutical industry standard
- Provide the documentary system that can meet FDA, cGMP requirements
- Provide FAT testing documents for complete machine
- Communication and cooperation with the international mainstream research field / grasp the advanced internal technological quality to synchronize with the international



