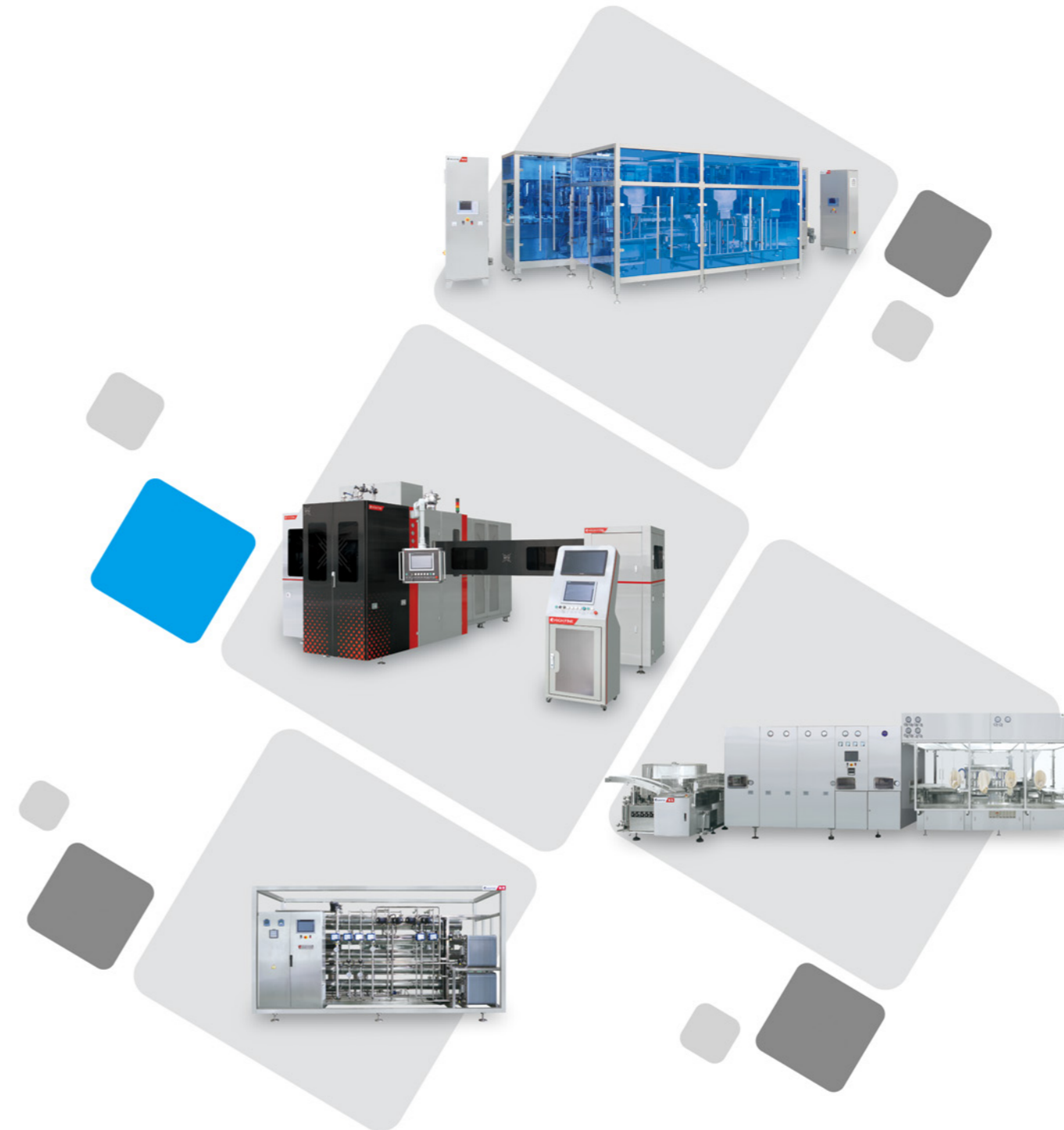




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TECHNOLOGY LEADER INDUSTRY MODEL



## Highfine Engineering Ltd

### Marketing

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### Factory

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E-mail: [highfinegroup@126.com](mailto:highfinegroup@126.com) <http://www.highfinegroup.com>

National Service Hotline: 400-153-1588

FDA standard water system  
Mainstream supplier of global water system equipment  
Mainstream supplier of global filling equipment



## Bottle Blowing-Filling-Sealing Machine (BFS)

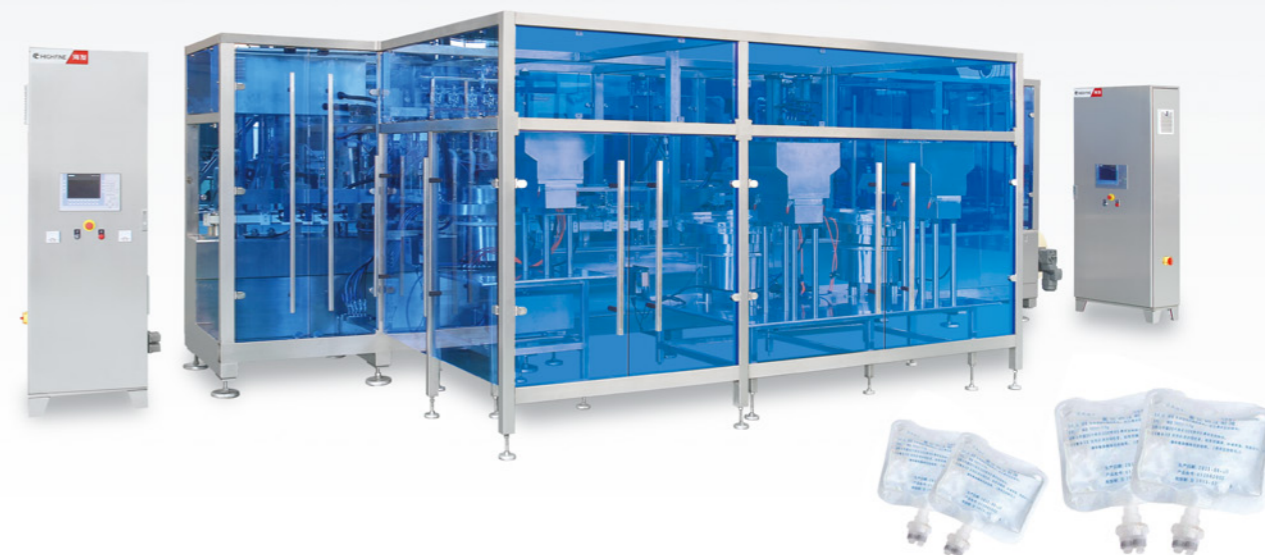


### Main application

Bottle Blowing-Filling-Sealing Machine (BFS) is a aseptic packaging technology. The system can ensure the process such as pharmaceutical grade PP/PE particles extrusion into container, automatic filling and sealing under aseptic conditions. It can effectively reduce the pollution of human operation, environment, material and so on. It meets the requirements of aseptic production process which is widely applied to various areas of plastic bottle sterile liquid preparation.

### Main technical parameters

Product model	HQS -20-A	HQS -20-B	HQS -30-A	HQS20 -30-B	HQD-6	HQD-8	HQS -20-2	HQS -12-2	HQS -16-2	HQS -30-2A	HQS -30-2B	HQD -6-2	HQD -8-2
Mould	1						2						
Tube embryo number	4	3	6	8	4	3	6	8					
Single embryo number	5	4	5*2	10	1	5	3	4	5*2	10	1		
Total cavity number	20	16	30	30	6	8	40	24	32	60	60	12	16
Filling range (ml)	2-20	5-30	0.2-0.8	1-2	500-1000	50-500	5-20	10-30	5-30	0.2-0.8	1-2	500-1000	50-500
Capacity (pcs/h)	6000	5400	9000	9000	1000-1100	1600-1800	12000	7200	9600	18000	18000	1800-2000	3200-3600
Shape size (mm)	5500×2800(6000)×3000				6000×3500×3000		6000×5000(10000)×3000				6000×6000×3000		



## Non-PVC Film Soft Bag Infusion Production Line

### Main application

Non-PVC film soft bag infusion production line is designed and manufactured by Highfine Engineering LTD, which is based on foreign advanced technology and meets the requirements of domestic and foreign customers. Non-PVC multi-layer co-extruded film bag infusion, with the characteristics of non-toxic, strong compatibility with liquid, water barrier, long guarantee period, resisting 121 °C high temperature sterilization, anti-low temperature, easy to transport and empty bag recycling not pollutes the environment, which has become the most popular soft bag infusion production line in the world.

### Main technical parameters

HSRD single hard tube series of soft bag infusion production line

Product model	HSRD1200	HSRD2500	HSRD3500	HSRD4500	HSRD6000
Output (pcs/h)	1200	2500	3500	4500	6000
Infusion bag specification (ml)	100-1000	100-2000		100-500	
Bag width of Infusion bag (mm)	120 135				
Filling accuracy	100ml±2% 250ml±1.25% 500ml±0.75% 1000ml±0.5% 2000ml±0.3%				
Power supply	380V 50Hz				
Power capacity (kW)	15	20	25	30	40
Total weight (kg)	2000	5000	6000	8000	10000
Overall dimensions (mm)	2940×2660×2250	6000×2660×2250	6100×2660×2250	7865×2660×2250	9090(10020)×2660×2250

HSRDS double hard tube series of soft bag infusion production line

Product model	HSRDS1000	HSRDS2000	HSRDS3000	HSRDS4000	HSRDS5000
Output (pcs/h)	1000	2000	3000	4000	5000
Infusion bag specification (ml)	100-1000	100-2000		100-500	
Bag width of Infusion bag (mm)	120 135				
Filling accuracy	100ml±2% 250ml±1.25% 500ml±0.75% 1000ml±0.5% 2000ml±0.3%				
Power supply	380V 50Hz				
Power capacity (kW)	18	25	30	40	50
Total weight (kg)	2000	5500	6500	8500	11000
Overall dimensions (mm)	2940×2660×2250	6000×2660×2250	6100×2660×2250	7865×2660×2250	9090(10020)×2660×2250



## HABL Series Ampoule Washing-Sterilization-Filling-Sealing Linkage Line



### Main application

The linkage line consists of HQCLA series vertical ultrasonic washing machine, HSDH series hot air circulation sterilization tunnel, HSA series filling and sealing machine. The model can be used in combination or in a single machine. The linkage line can complete water spray filling, ultrasonic cleaning and flushing (internal and external), CA flushing (internal and external), preheating, drying and sterilizing to remove pyrogen, cooling, before and after nitrogen, sealing after preheating, sealing and other processes.

This line can meet the size ranging from 1-20ml ampoule of washing, drying and sterilizing to remove pyrogen, filling and sealing requirements of the production process.

### Characteristic

Vertical ultrasonic washing machine using ultrasonic rough washing, circulating water, WFI and clean compressed air sprays and cleans the container alternately. Cleaning clarity and visible material detection effect is ideal; It is one of the most popular cleaning machine in the world today.

The sterilization tunnel adopts the principle of hot air laminar flow and high temperature sterilization process to preheat, dry, sterilize, remove heat and sterilization process. It is one of the most popular drying and sterilizing machines in the world.

Filling and sealing machines adopts step-by-step bottle conveying, positioning filling, wire drawing and sealing. The sealing rate is high. It is one of the most popular filling and sealing machines in the world.

The interlocking production line adopts PLC control and touch screen operation, which can be used for linkage control or stand-alone operation. The control runs stably and with high automation.

### Main technical parameters

Product model	HABL-6	HABL-8	HABL-10	HABL-12	HABL-16
Suitable sizes (ml)	1-20ml (ampoule)				1-10ml (ampoule)
Output (pcs/h)	6000-16000	8000-21000	10000-24000	12000-30000	16000-36000
Filling heads	6	8	10	12	16
Power supply	380V 50Hz				
Power capacity (kW)	78	78	80	90	90
Total weight (kg)	8900	8900	9400	9700	10100
Overall dimensions (mm)	9100×2200×2450	9100×2200×2450	9260×2200×2450	9910×2200×2450	10042×2200×2450



## HXLL Series Vial Washing-Sterilization-Filling-Stoppering Linkage Line



### Main application

The linkage line consists of HQCLA series vertical ultrasonic washing machine, HSDH series hot air circulation sterilization tunnel, HSFSG series filling and stoppering machine. The model can be used in combination or in a single machine. The linkage line can complete water spray filling, ultrasonic cleaning and flushing (internal and external), CA flushing (internal and external), preheating, drying and sterilizing to remove heat source, cooling, filling, sealing, capping and other processes etc.

This line can meet the size ranging from 2-30ml vials of washing, drying and sterilizing to remove heat source, filling and sealing requirements of the production process.

### Characteristic

Vertical ultrasonic washing machine using ultrasonic rough washing, circulating water, WFI and clean compressed air sprays and cleans the container alternately. Cleaning clarity and visible material detection effect is ideal; It is one of the most popular cleaning machine in the world today.

The sterilization tunnel adopts the principle of hot air laminar flow and high temperature sterilization process to preheat, dry, sterilize, remove heat and sterilization process. It is one of the most popular drying and sterilizing machines in the world.

The filling and stoppering machines adopts V shape block to transfer and reciprocating tracking filling which can ensure stable vials transfer, full time of filling and accurate filling volume, using the way of progressive stoppering to ensure high qualification rate. It is one of the most popular filling and sealing machines in the world.

The interlocking production line adopts PLC control and touch screen operation, which can be used for linkage control or stand-alone operation. The control runs stably and with high automation.

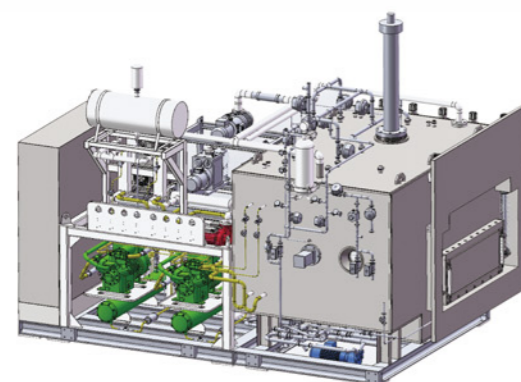
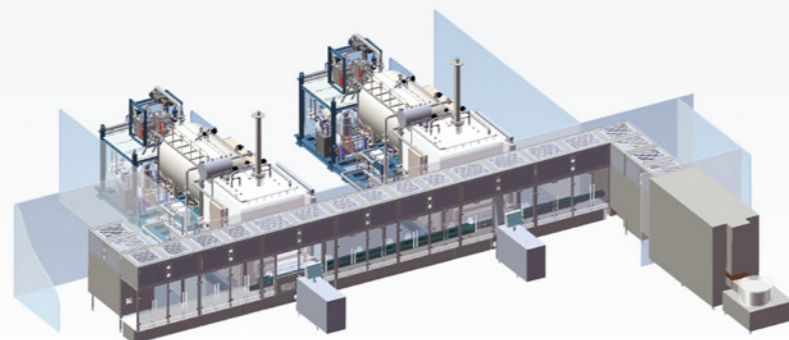
### Main technical parameters

Product model	HXLL-2	HXLL-4	HXLL-6	HXLL-8	HXLL-10	HXLL-12	HXLL-16	HXLL-20
Suitable sizes (ml)	2-30 (vial)							
Output (pcs/min)	20-60	40-120	60-200	100-250	120-300	150-400	200-500	280-600
Filling heads	2	4	6	8	10	12	16	20
Power supply	380V 50Hz							
Power capacity (kW)	79	79	90	92	108	108	115	132
Total weight (kg)	8500	8500	8800	9300	9900	10200	10800	11800
Overall dimensions (mm)	9050×2200×2450	9050×2200×2450	9700×2200×2450	9700×2200×2450	10850×2200×2450	10850×2200×2450	11770×2200×2450	13653×2200×2450

## Freeze drying system solution

### Best freeze-drying technology

We have prepared for your choice depending on our experience in pharmaceutical manufacturing and service. We will provide customized products with more flexible and better services for you.



### Lyophilizer

- The products fully reflect the stability and reliability of High Fine lyophilizer in LYOHF series. SIP and CIP are optional.
- Organic solvents, high-risk formulation and ATEX are optional.
- The optimized industrial design is easy to clean without dead angles.
- Independent, professional and reliable software development; HMI interface is friendly and practicable.

### Lyophilizer selection table

	LF experimental type	HF productive-oriented											
Shelves loading usable area (m <sup>2</sup> )	0.5	1	2	5	7.5	10	15	20	25	30	35	40	
Water catch capacity (kg)	10	20	40	100	150	200	300	400	500	600	750	800	
Φ16 mm vial	1900	4600	10550	20880	32500	41750	61900	85100	100550	125700	150800	174000	
Φ22 mm vial	1000	2450	6150	11050	17200	22100	32700	45000	53200	66500	79800	92100	
Bulk solution quantity (L)	10	20	40	100	150	200	300	400	500	590	590	800	
Shelves size	Width (mm)	300	450	600	900	900	900	1200	1200	1200	1500	1500	1500
	Length (mm)	450	600	900	900	1200	1200	1200	1500	1500	1500	1800	1800
Shelves quantity	4+1	4+1	5+1	6+1	7+1	9+1	10+1	11+1	13+1	13+1	13+1	15+1	
Spacing (mm)	80	100~120 (depends on customers requirements)											
Temperature range of shelves (°C)	-55, +70	-55, +70											
Temperature of cold trap (°C)	≤-70	≤-70											
Ultimate vacuum (Pa)	1	1											
Installed power (kW)	8	10	16	33	45	55	70	105	120	144	163	180	
Cooling water quantity (m <sup>3</sup> /h)	3	5	7	11	16	18	25	37	37	42	50	50	
Compressed air (MPa)	0.1 (0.5~0.7)	0.1 (0.5~0.7)											
length (mm)	1000	2650	3700	4800	5000	5800	6200	9100	9100	8900	9200	9200	
Width (mm)	850	1600	1800	2380	1600	5730	5730	4715	4715	5730	5730	5730	
height (mm)	2200	2500	3000	3400	3160	5000	5150	5465	5730	6250	6250	6250	
Equipment weight (kg)	440	1500	2200	7000	9000	12000	17000	23800	28000	31000	34000	36000	
Pure steam consumption (kg/h)	—	60	100	130	150	200	230	280	320	380	380	450	
Pure water/WFI quantity (l/min)	—	60	90	120	150	160	200	230	260	280	280	300	

## Automatic loading and unloading system

The automatic loading and unloading system of lyophilizer is suitable for filling process between aseptic liquid filling line and freeze dryer, and the unloading process between the freeze dryer and the aseptic capping machine production line. Thus it can realize the continuous transmission of vials of the whole line as well as perfectly combine with the aseptic isolation system to keep the product in the corresponding aseptic and clean environment.

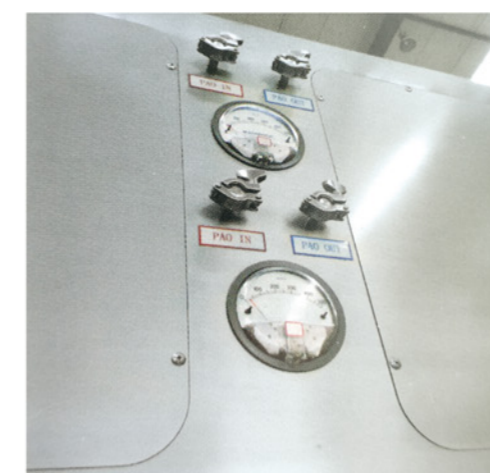
### Mobile automatic loading and unloading system

- It can complete the loading and unloading of many lyophilizers.
- Design method of door cover small door of aseptic indoor lyophilizers.
- One shelf can complete loading and unloading at one time.
- The isolator is suitable for LAF and oRABS.
- It can handle vials with wide range specification.
- Feeding speed is up to 400-600vpm (determine according to the specific bottle type).



### Fixed automatic loading and unloading system

- It can complete the loading and unloading of many lyophilizers.
- The door of lyophilizer is designed as a routine overhaul and is located in the machine repair room. The lyophilizer in aseptic room is designed only with a small door for loading and unloading.
- Aseptic isolator is suitable for LAF, RABS, cRABS, ISOLATOR.
- It is suitable for low temperature feeding technique, and vials are directly loaded into the shelf of low-temperature-control lyophilizer.
- One line for two purposes: both lyophilized powder and water-solubility injection production lines.
- Compact layout design, cover a small area.
- Feeding speed is up to 400-600vpm (determine according to the specific bottle type).



### Isolator

Isolator is an air purification unit providing locally clean environment. Its principle is that the air passes through the high efficiency filter with a certain air pressure through the air compressor. Then by means of equalizing flow film, the clean air can press the original air out of the working area like a piston, so as to ensure that the working area quickly reaches the cleanliness required by the process.

Isolated laminar hood can be arranged flexibly above the process points requiring high cleanliness. It can be used individually or in multiple combinations of ribbon clean areas. It is installed in the form of suspension and floor stand. The isolator mainly has the top air inlet, side air inlet and flange air inlet. The isolator can be customized by customer's actual room layout.

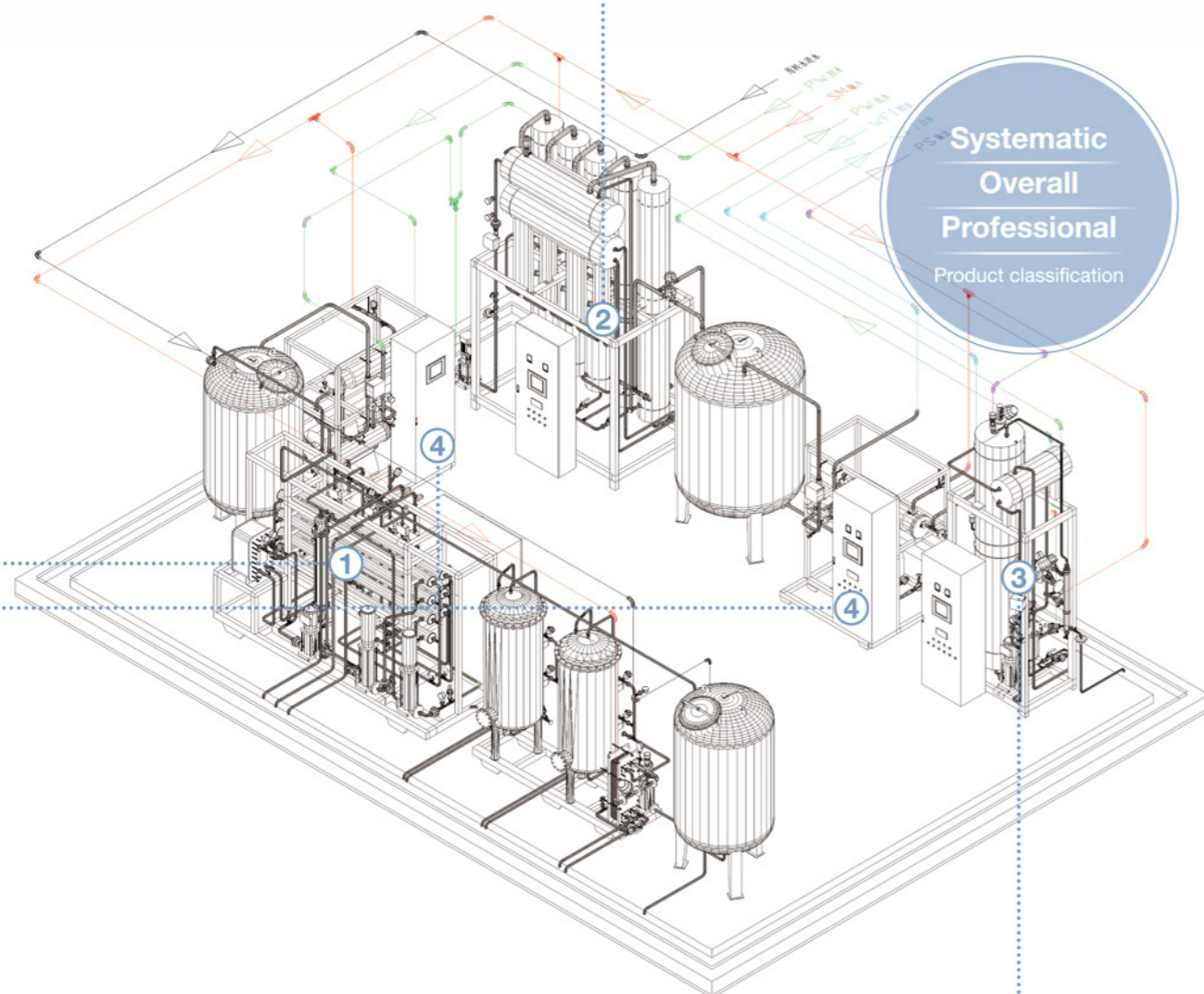
## Water system equipment

### Purified water system

The purified water system adopts modular design enabling the system to have various characteristics, such as independence, modularization and simple operation, etc. These functions ensure the consecutiveness, stability and reliability of the equipment. 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, including pretreatment configuration combined with 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.

### Multi-effect water distiller

Distillation is the technical process for chemical and microbiological purification of raw water through steam-liquid phase transition method and separation. During this technical process, the water is evaporated and the steam produced isolated from the water. What's more, the unevaporated water flows back to 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 contained may decrease through distillation.



### Storage distribution system

### ⑤ On-line cleaning system

### ⑥ Biological products tank in batching system

### Pure 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 be taken as feeding water of pure 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.

## 1 Purified Water System

### Hot water disinfection purification water system

#### Pure water equipment requirements

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



## 2 Multi-effect Water Distiller

### B series multi-effect water distiller

B series multi-effect water distiller adopts rising film and multi-stage separation to evaporate. The industrial steam enters the evaporator, passes through valves and interchanges heat with the purified water rising film in the tube. The purified water after heat exchange becomes vapour. Then impure heat source will be removed from the vapour through separation device 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 differential pressure. After that, it will enter the storage tank through the pipes. The concentrated water without evaporation and separation shall enter the next effect for re-evaporation through concentrated water inlet.

#### Equipment features

- Adopt 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 for each effect accurately to reduce raw water loss.
- No need to exchange the multi-stage separation device and life-span of the equipment can be extended.



### 3 Pure Steam Generator

#### Production capacity

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

#### 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 requirement:  $500/1.7=294\text{kg/h}$
- Model selected: PSG 300 DTS



### 5 On-line Cleaning System CIP workstation

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 widely used in the plants, such as food, drinks and pharmacy, etc. CIP device can not only clean the machine, but also control the cleaning methods of microorganism.

#### CIP cleaning device has the following advantages

- Can make the production plan reasonable and improve the production capacity.
- Compared with manual cleaning, CIP cleaning effect will not be affected due to different operators. The CIP device 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 three types, such as manual, semi-automatic and automatic operation, which can be selected by the users.



### 4 Storage Distribution System Pure water storage distribution system

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 chuck. The roughness of the surface contacting with the 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.



### 6 Biological Products Tank In Batching System

#### Automatic welding equipment that can manufacture stainless steel pressure vessel.

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

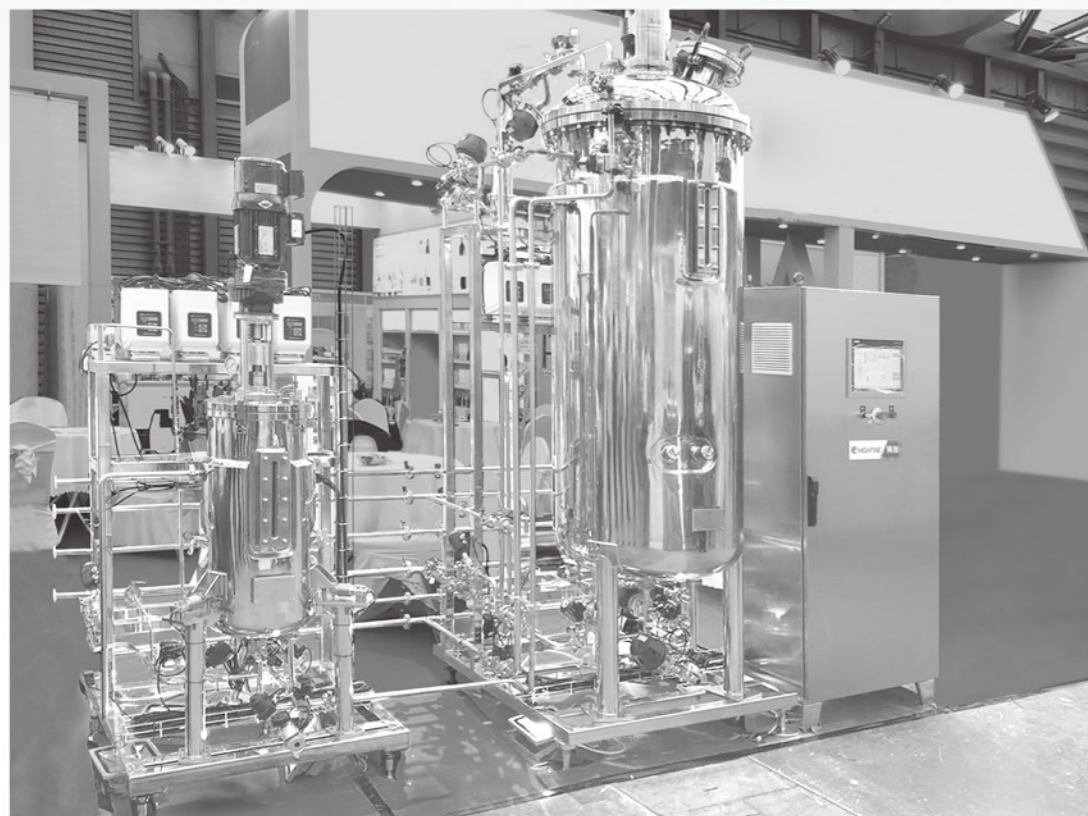
- 400# + electrobrightening Ra 0.4 $\mu\text{m}$   
400# + 600# + 800# + 2 electrobrightening Ra 0.28 $\mu\text{m}$
- Surface sandblasting and surface matte sanding Ra $\leq 0.6$
- Electrolytic polishing technologies and devices

#### 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. It also conforms to the relevant requirements for equipment installation.



## Fermentation Tank System



### About company

Highfine specializes in the design and production of various biochemical instruments such as liquid fermenters, solid fermentation equipment, special new biochemical reactors, etc. It can undertake turnkey projects such as various fermentation equipment, pilot fermentation workshops and large production bases.

The R&D team specializes in bioengineering, biochemical engineering, fermentation engineering, mechanical engineering, electrical and automation, computer technology and other fields, and can provide users with high-quality services including biological fermentation equipment, processes and products.

Applications include edible fungi, medicinal fungi liquid seed production, animal vaccines, biopharmaceuticals, biological fertilizers, biological feeds, enzyme preparations, organic acids, health foods, beverages and many other fields.

Fermentation system included: seed tanks, fermentation tanks, controlling system, air handling system, feeding system, piping system, valves, operating platforms, utilities etc. We manufacture the follow-up processing systems for users.

According to the requirements of the users, we can design the fermentation workshop and be responsible for on-site installation and commissioning. Our company also trains the employers for the clients and provide the GMP arguments to help users.

### The control parameters

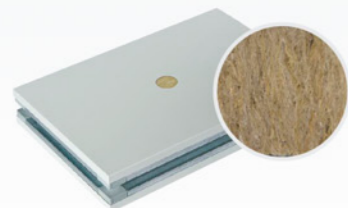
- Operating temperature: temperature of cold media +5°C-65°C;
- The control precision:  $\pm 0.2-0.5^{\circ}\text{C}$ ;
- The stirring speed: 0-500r/min;
- pH control range: 2-12 pH  $\pm 0.05$  pH;
- The measurement accuracy: 0-100% or 0-200%;
- Automatic pH, defoaming agent, feeding (peristaltic pump or pneumatic valve control).



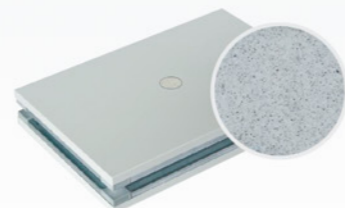
## Cleanrooms- Cold Rooms

### Sandwich panel types

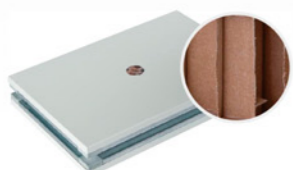
We can provide machine-made and hand-made sandwich panels of different types of materials for various applications.



**Rock Wool**  
High quality powder coated steel sheet, rock wool filler, and aluminum alloy frame or galvanized steel strip.



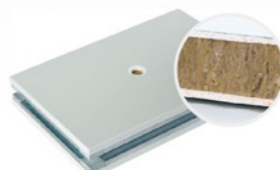
**Poly Urethane (PU)**  
High quality powder coated steel sheet, PU filler, and aluminum alloy frame or galvanized steel strip.



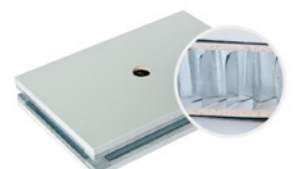
Paper Honeycomb



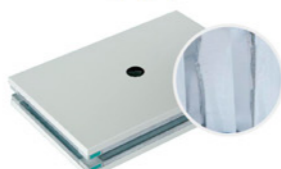
Hollow Magnesium Oxide (MgO) Board



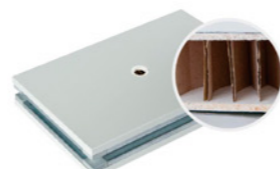
Magnesium Oxide (MgO) Board & Rock wool



MgO Board & Aluminum Honeycomb



Aluminum Honeycomb



MgO Board & Paper Honeycomb

### Cleanroom doors

We have a wide range of door designs, materials and colors, including embedded double glazing.



1. Color Steel Sandwich Panel
2. Machine-made Steel Panel
3. Hospital Type
4. Stainless Steel
5. Stainless Steel Frame With Color Panel
6. Aluminum Alloy Frame

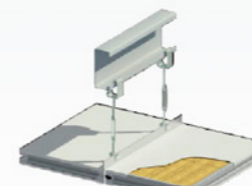
Design and produce with premium materials to ensure optimum performance and durability.



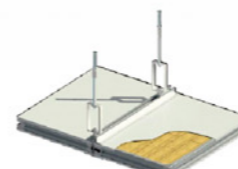
Lever Handle Lock   Round Handle Lock   C-Type Handle   Special GMP Lock   Auto Hinge   Special GMP Hinge   Stainless Steel Hinge   Electric Interlock

### Panel ceiling

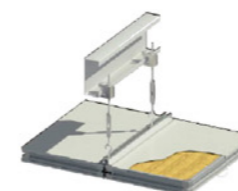
We offer different types of panel ceiling systems. We can provide advices or follow the specific requirements of cutomers.



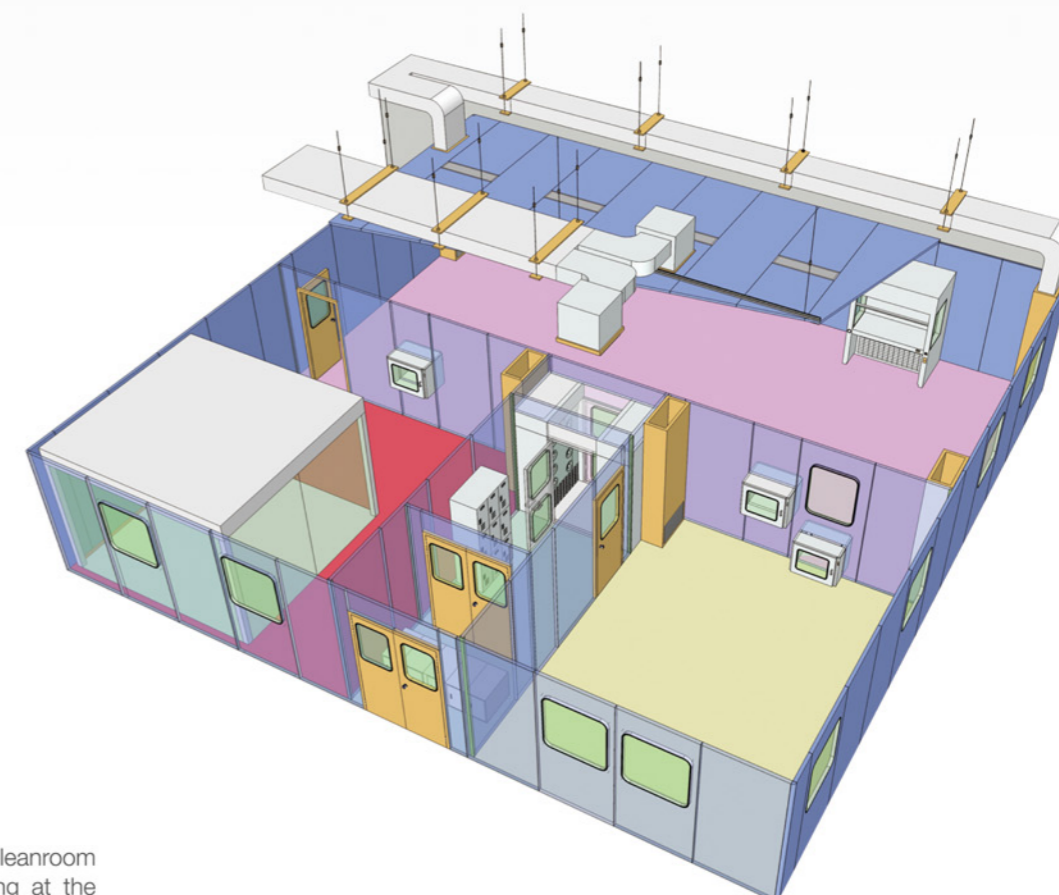
T - Grid Ceiling



I - Grid Ceiling



I - Grid Ceiling (hooks)



### Cove

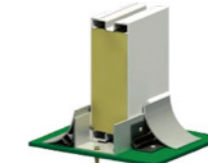
We have different types of cleanroom cove to facilitate the cleaning at the corners.



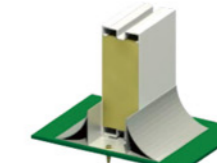
Vertical Corner



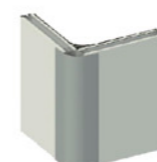
Circular Removable Corner



U-shaped Ground Track



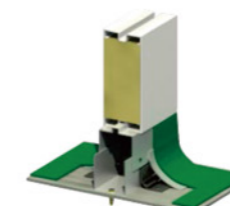
Double Circular Ground Track



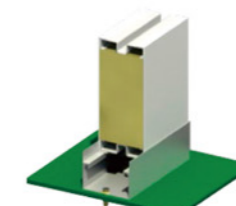
Circular Corner



Circular Flush Corner



Adjustable Ground Track



Waterproof Ground Track