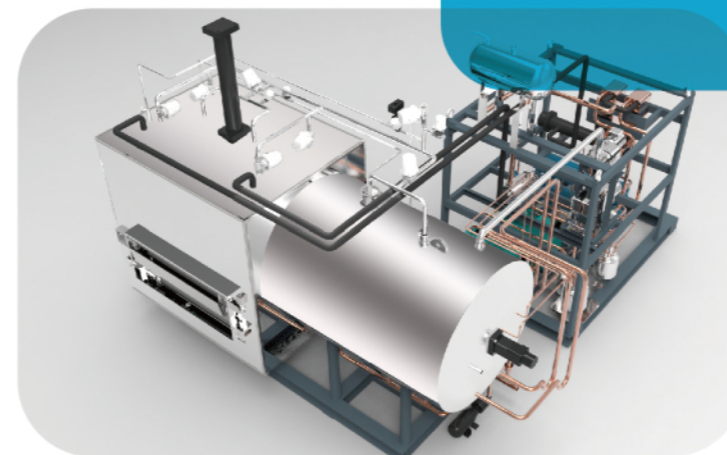




Integrated Solutions to Sterile Filling/Isolation/Freeze-drying System



Offices and Factories

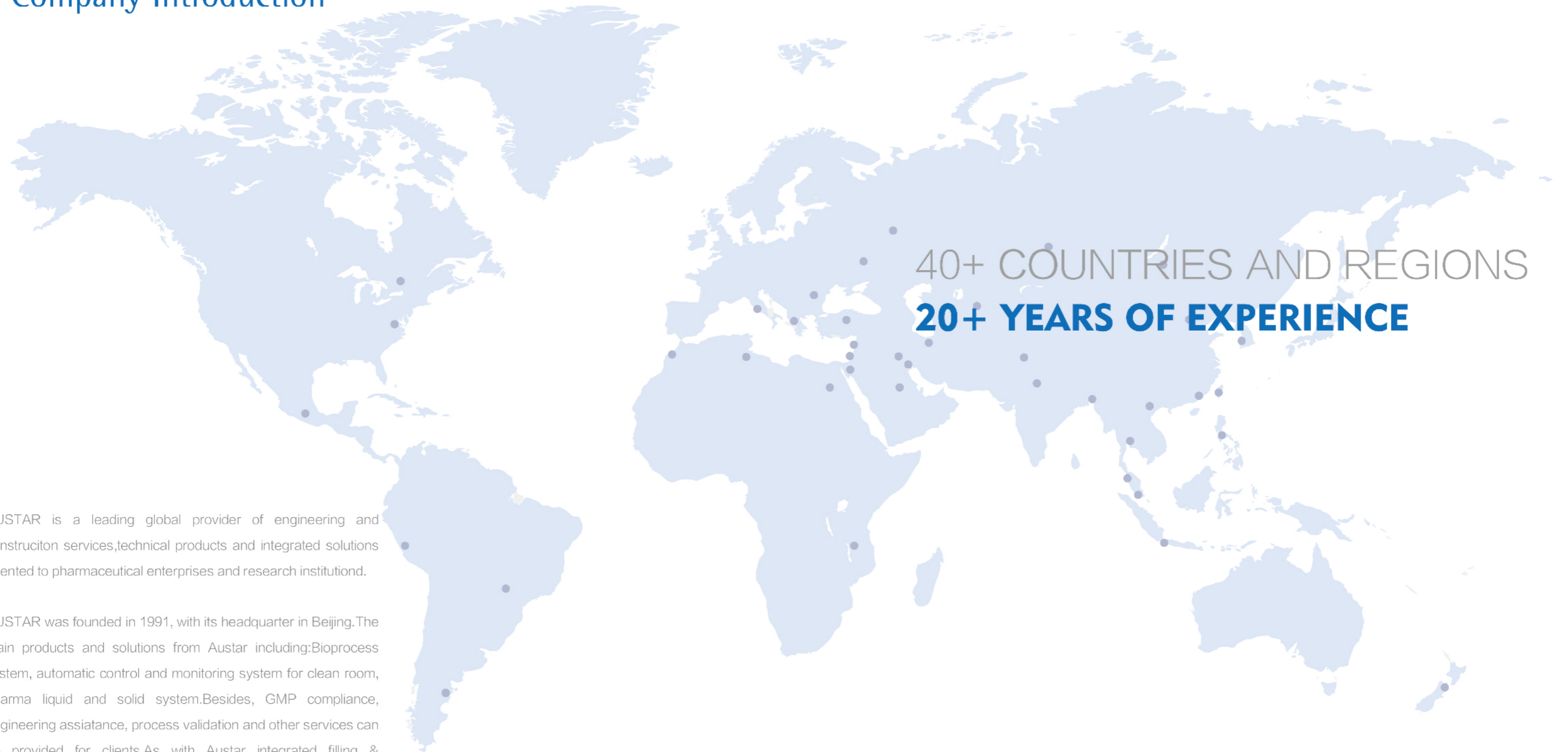
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Company Introduction



AUSTAR is a leading global provider of engineering and construction services, technical products and integrated solutions oriented to pharmaceutical enterprises and research institutions.

AUSTAR was founded in 1991, with its headquarter in Beijing. The main products and solutions from Austar including: Bioprocess system, automatic control and monitoring system for clean room, pharma liquid and solid system. Besides, GMP compliance, engineering assistance, process validation and other services can be provided for clients. As with Austar integrated filling & freeze-drying solutions: Advanced vial filling line, ampoule filling line, freeze drying system, isolator, inspection machine and packaging machine can be integrated for the whole project. Our goal is to deliver high quality technology equipments and high-end integrated engineering solutions for global pharmaceutical market. Austar is committed to promoting pharmaceutical industry advancement and becoming your partner in improving human health.





01



Integrated Solutions to Sterile Filling
Isolation / Freeze-drying System

02



Key Equipment of Integrated System

- Filling line (ROTA)
- Freeze Dryer
- Intelligent Freeze-drying Control System
- Isolation System
- Automatic Loading And Unloading System

03



Validation Service
After-sales Service



AUSTAR and Freeze-drying

AUSTAR & Freeze-drying

- 1 Since 1990, AUSTAR has been devoted to promoting the development of freeze-drying industry, and provided customized products and services for over 50 pharmaceutical enterprises and R&D institutions.
- 2 As the first company of introducing foreign advanced large-scale freeze dryer and freeze-drying technology for API, AUSTAR makes outstanding contributions for the development of intermediates such as 6APA, 7ADCA and 7ACA, and its downstream cephalosporin antibiotics and ferment antibiotics.
- 3 In 1999, AUSTAR cooperated with STERIS GmbH (Leybold in origin), which used to be the global leading manufacturer for freeze dryer and automatic loading and unloading system. Freeze dryer is widely used in European, American and Asian pharmaceutical enterprises and well appraised by customers.
- 4 The first freeze-drying line, equipped with automatic loading & unloading isolation system and VHP decontamination system, was developed and designed by STERIS GmbH.
- 5 In particular, the successful application of this system promotes the development of VHP decontamination technology and sterile isolation technology.

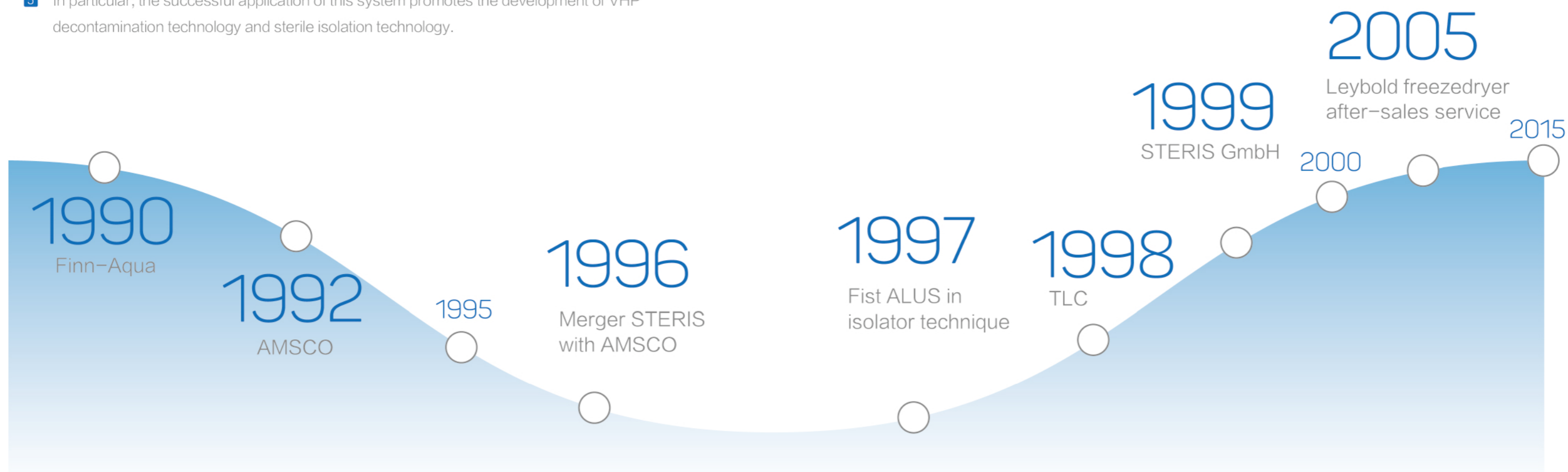
Development History

AUSTAR is devoted to the development of freeze-drying technology, with its knowhow on freeze-drying technology over years.

The freeze dryer business division of AUSTAR was founded in Nanjing in 2008. Since the establishment of this division, AUSTAR continually introduced international leading designers into China, establishing IFF design team and committing to pharma industry development.

After the first production of the AUSTAR freeze drying line, AUSTAR held the product launch successfully in Nanjing in October of 2015, and more than 100 Chinese customers participated in this launch.

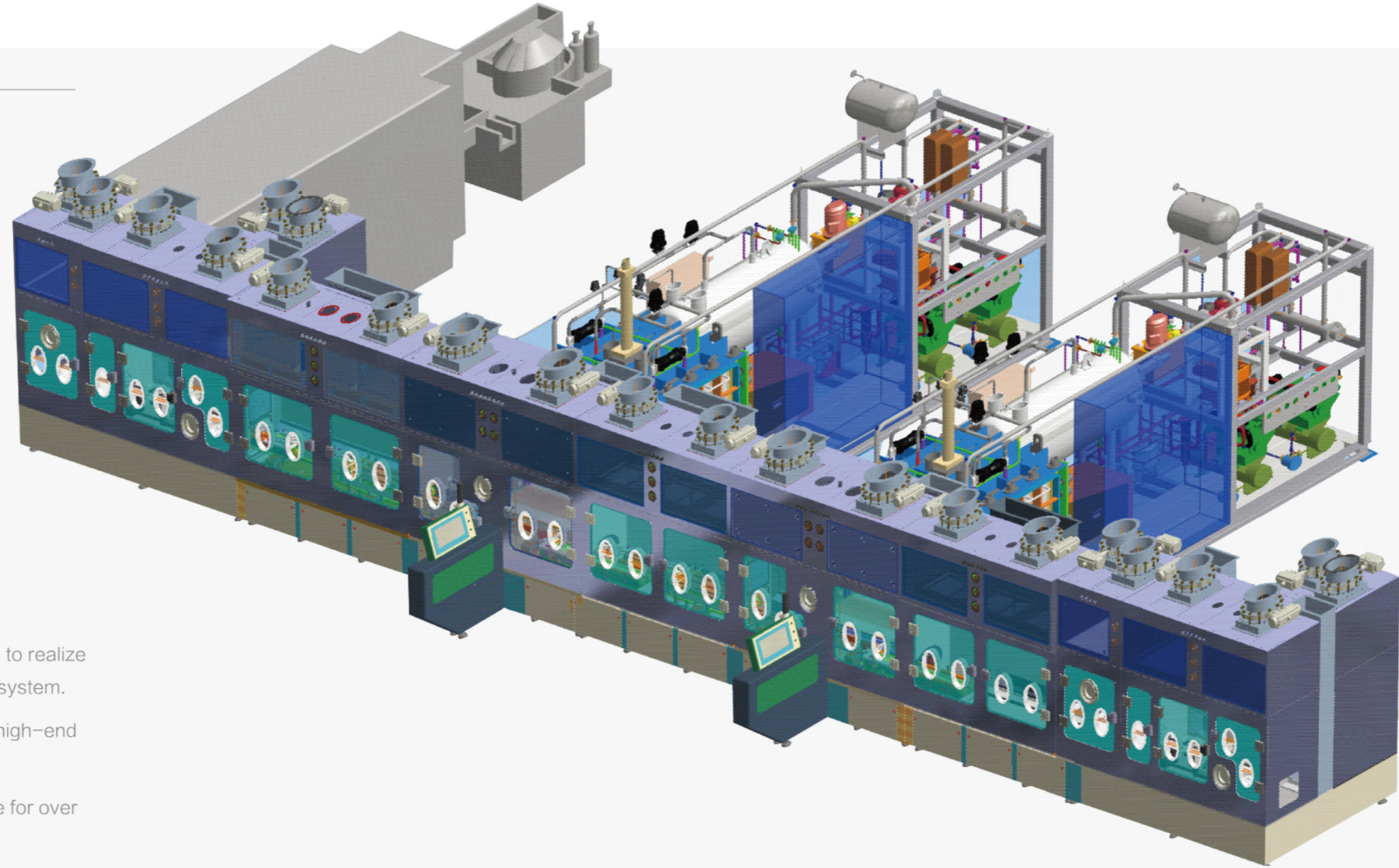
Later, this freeze-drying production line was displayed in Wuhan CIPM in October, 2015.



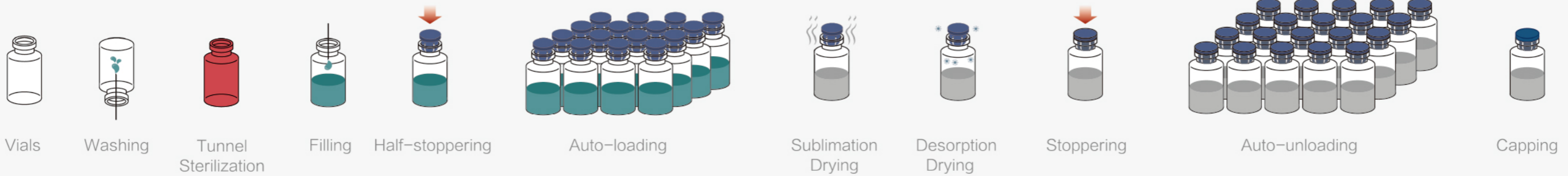
Integrated Freeze-drying / Isolation / Capping System

Product Description

AUSTAR provides the latest sterile filling and freeze-drying integrated system in Europe, and adopts advanced European technical standards for designing and manufacturing.



- 1 Cooperate with Germany ROTA and America Steris to realize the integration of filling, isolation and freeze-drying system.
- 2 Comply with enclosed isolation system required by high-end bio-pharmaceuticals
- 3 Possess domestic leading validation team to service for over 100 domestic pharmaceutical enterprises.
- 4 Comply with cGMP and FDA requirements.



ROTA Integrated Lines for Washing, Sterilizing, Filling and Closing

Product Description

AUSTAR provides customer with the integrated sterile preparations filling line. The filling line is used for the washing, sterilizing, filling, sealing, and labeling of ampoules, vials, cartridges, and pre-filled syringes. According to the customers' requirements, we can provide comprehensive process design for the washing, sterilizing, filling, and capping of freeze-dried vials, which complies with sterile filling requirements.

The filling volume of vials can be up to 250ml.

Highlights

1 Energy Saving

- Specilised design for air recycling system of sterilizing tunne
- Multi-servo design, with stable operation and lower energy consumption
- Germany high precision machining technology for reducing equipment abrasion degree effectively

2 Space Saving

L-shaped, U-shaped, 90° angle customization design according to customer's room condition. More reasonable layout

3 Multi-purpose Design

It can simultaneously satisfy the processing requirements of ampoules, vials, pre-filled syringes, etc

4 Bottle Washing Machine

- Multi-station,multi-angle washing,no dead zone for washing
- Bottle breakage rate of less than 0.01%
- Full servo-control, simple and quick cleaning design

5 Sterilizing And Drying Tunnel

- Double-panel temperature control, with uniform temperature distribution
- Being controlled by automatic isolation door to avoid transverse heat transfer
- High temperature anemometer being used for monitoring the tunnel

6 Filling Machine

- Multi-servo control, stable machine operation, and 100% completeness rate.
- High filling accuracy of within $\pm 0.5\%$
- Low maintenance cost
- Multi-dimensional sterile control assurance

7 Capping Machine

- Fully applicable to domestic packaging materials
- Elegant capping appearance
- Stable operation
- Low maintenance cost

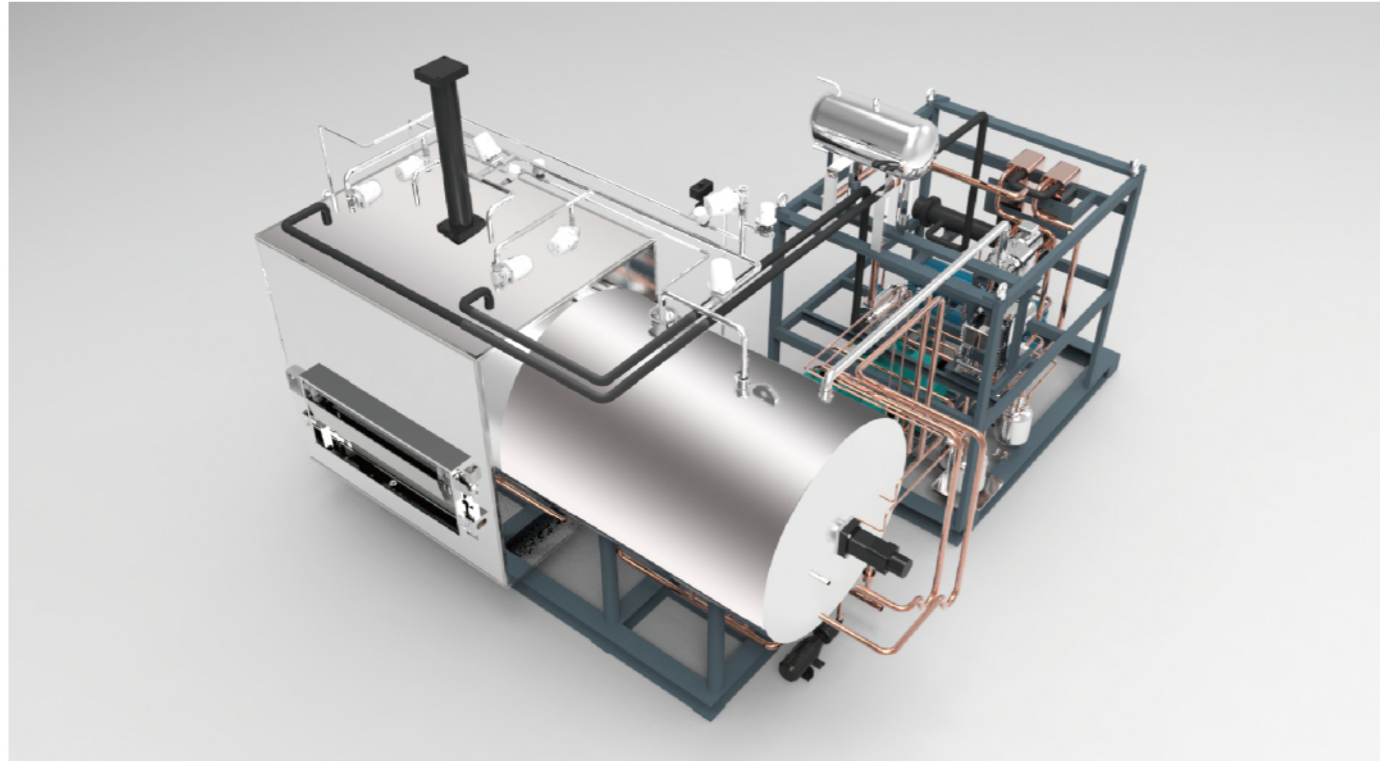


① Bottle Washing Machine

② Sterilizing And Drying Tunnel

③ Filling Machine

Product Description



3D model diagram of freeze-drying system

AUSTAR devotes itself to providing intelligent freeze dryer with the purpose of product protection. As the core equipment for the production of sterile preparations, the freeze dryer of Austar is designed and constructed with European technical standard. All systems are conducted full test under the condition of actual production. The industrial production freeze dryer provided by AUSTAR can be used to freeze-dry API in vials or plates, which complies with the requirements of cGMP and FDA, as well as pharmaceutical industry and bioengineering manufacturers.

Austar can provide 2-40m² industrial production freeze dryer.



Features and advantages

1 cGMP Compliance

- The big fillet and bottom of drying cabinet shall be designed with bi-directional slope to facilitate drainage.
- Fixed nozzle and auxiliary spray ball are used for cleaning to ensure the cleaning effect.
- Special design for hose on the shelf facilitates cleaning.
- The sight glass on the cabinet adopts indent form to facilitate cleaning.

4 Equipment Safety And Stability

- The freeze dryer is equipped with automatic door-lock to ensure the safety of equipment
- Vacuum system and refrigeration system are tested by chlorine strictly to reduce system leakage greatly.
- Unique control system and high quality product components can reduce the risk of product contamination.

5 Convenient Maintenance

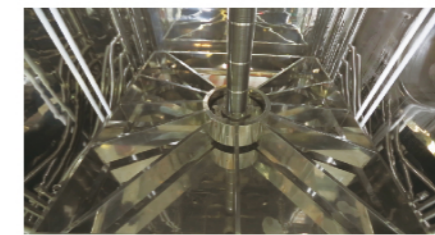
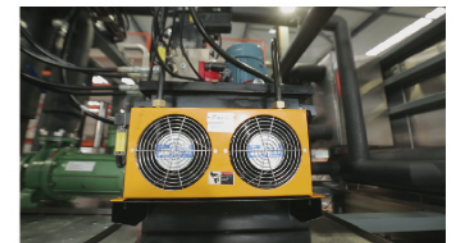
- The doors of different sizes adopt uniform design for seal rings, which is simple and easy for maintenance
- All sensors are connected by sanitary clamp, which is easy for disassembly.

2 High Efficiency And High Performance

- Vacuum/refrigeration/heating/water capture and other index are designed/—tested in compliance with European standards
- Electronic expansion valve is adopted to facilitate the stability and controllability of shelf and cold trap temperature.
- The design of condensing coil and channel of mushroom valve can increase water capture efficiency

3 Product Safety Guarantee

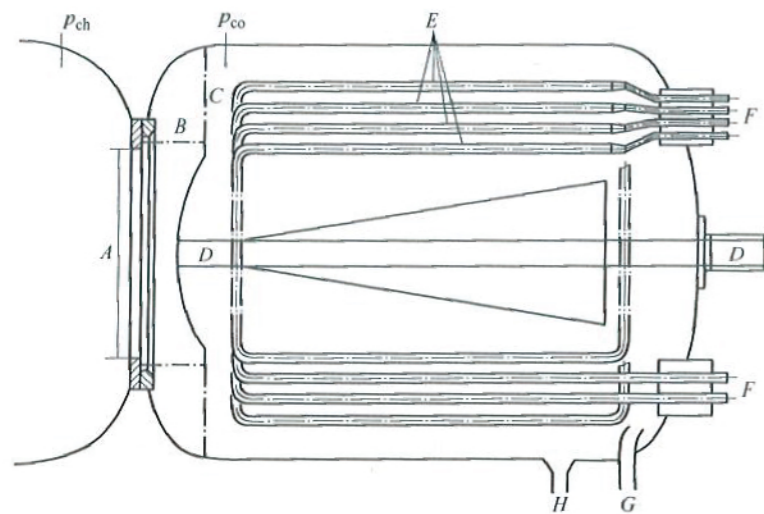
- The design by AUSTAR is based on the concept of product protection.
- Unique control system and high quality product components can reduce the risk of product contamination.
- All critical systems adopt redundant design.



Condenser Design

The design of condenser has direct influence on ice capture efficiency, freeze-drying period and load of refrigerating system

- 1 Non-uniform ice capture will decrease coil refrigeration area, and affect ice capture efficiency.
- 2 The ice density is big, which eradicates "snow ice", and has higher heat exchange efficiency.
- 3 High efficiency ice capture technology can reduce refrigerating unit load, and avoid water vapor entering into vacuum pump to cause damage

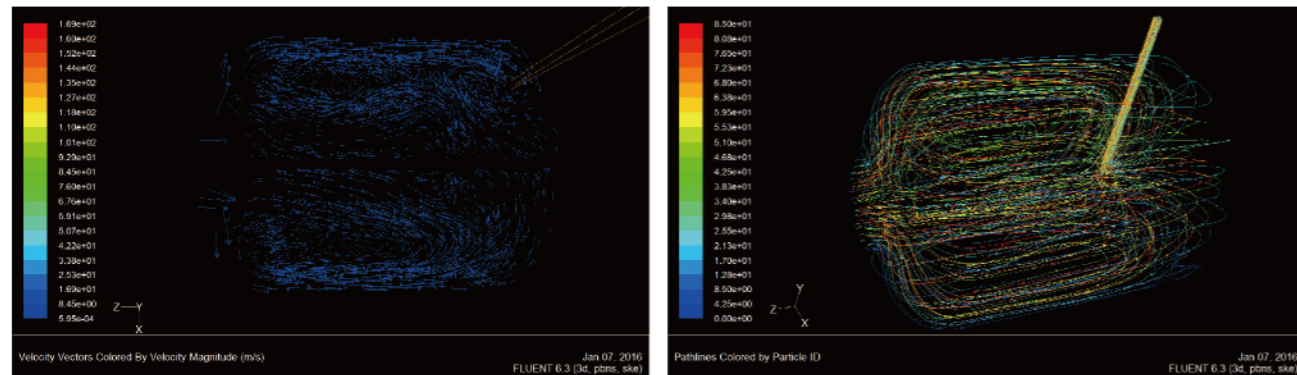


- A. Port connected to freeze-drying cabinet;
- B. Cylinder hole is moved by D
- C. Channel between valve plate and condenser;
- D. Valve plate and hydraulic valve drive device;
- E. Condensation surface of freezing coil;
- F. Inlet and outlet of coolant;
- G. Pipe connected to vacuum pump;
- H. Drain hole during defrosting of water vapor condenser; P_{ch} and P_{co} are the pressure in drying cabinet and condenser respectively.

Schematic diagram of cold trap of freeze dryer

Air Pattern Test for Coils

Study the air flow pattern in freeze dryer by using 3D mock test technology to prevent the formation of turbulence.

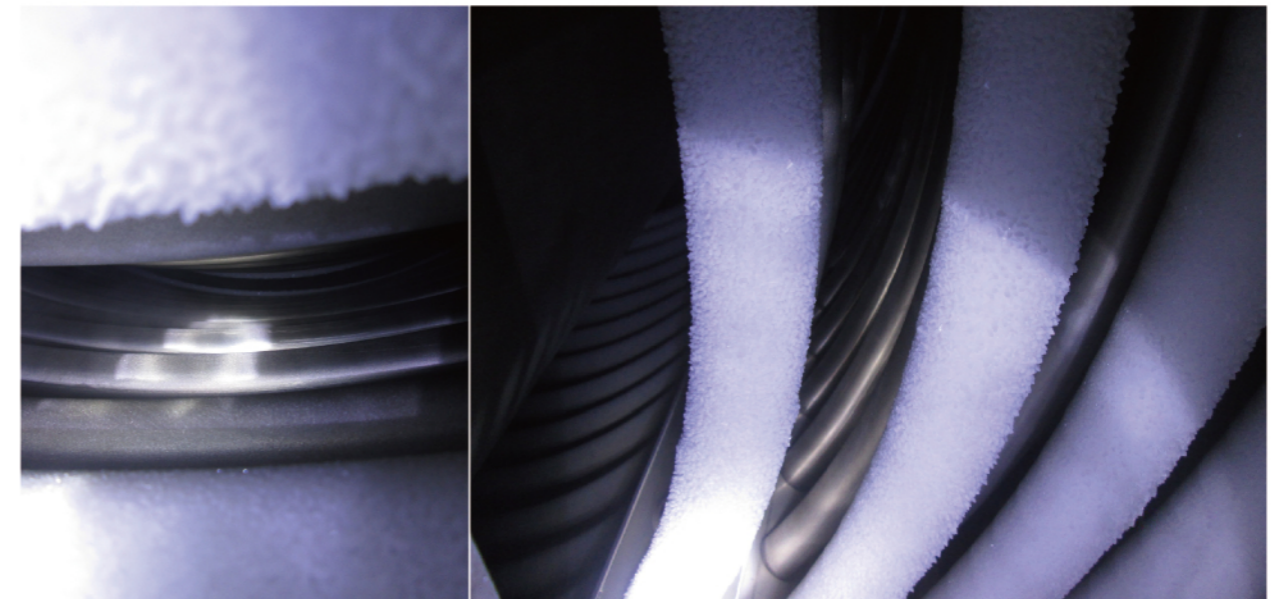


Highlights

Freeze-drying curve is smooth and steady, vacuum and temperature control is uniform and stable.



Ice-capture Picture in AUSTAR Freeze Dryer

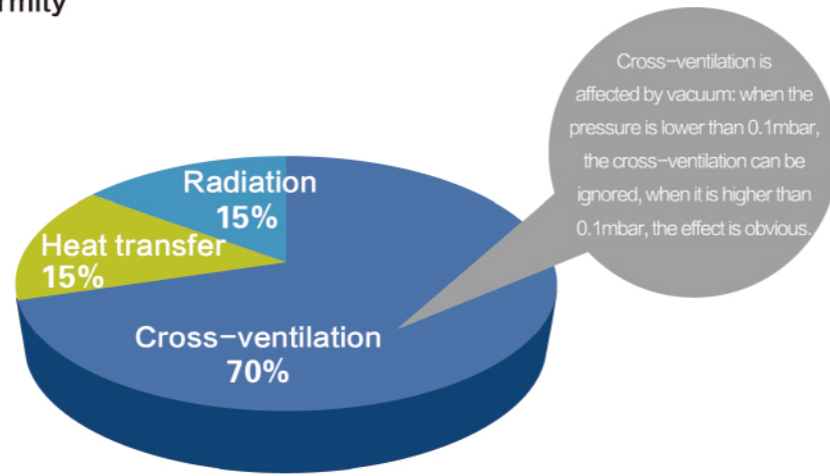


Bad Ice-capture

Assurance of product temperature uniformity

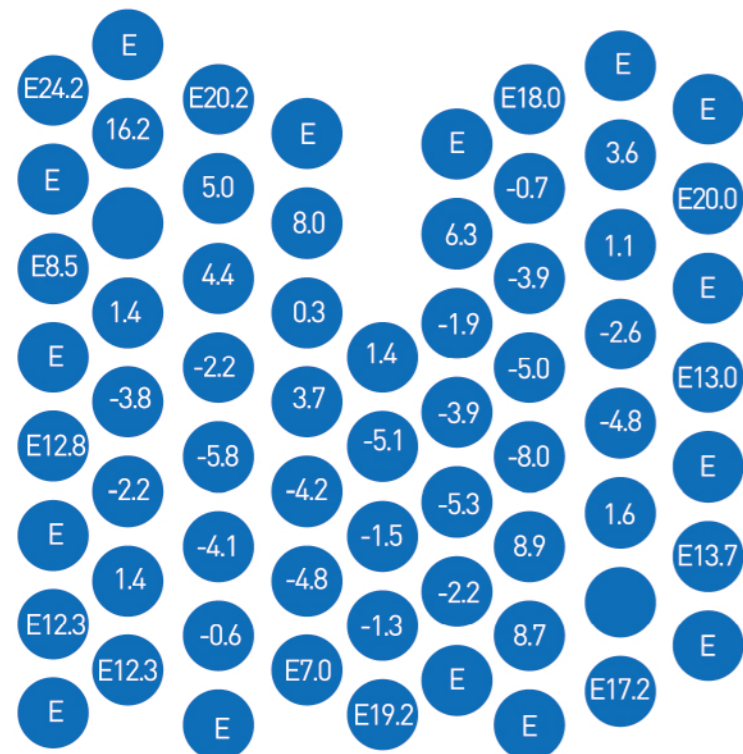
Advanced design concept adopted by Germany freeze dryer, customized analysis of drug heating. The equipment is designed optimally to ensure the product temperature uniformity.

1. Shelf processing technology
2. Wall temperature radiation control
3. Air cross-ventilation effect control



Heat transfer ratio of freeze-dried drug products:

Distribution of vials on the shelf of freeze dryer

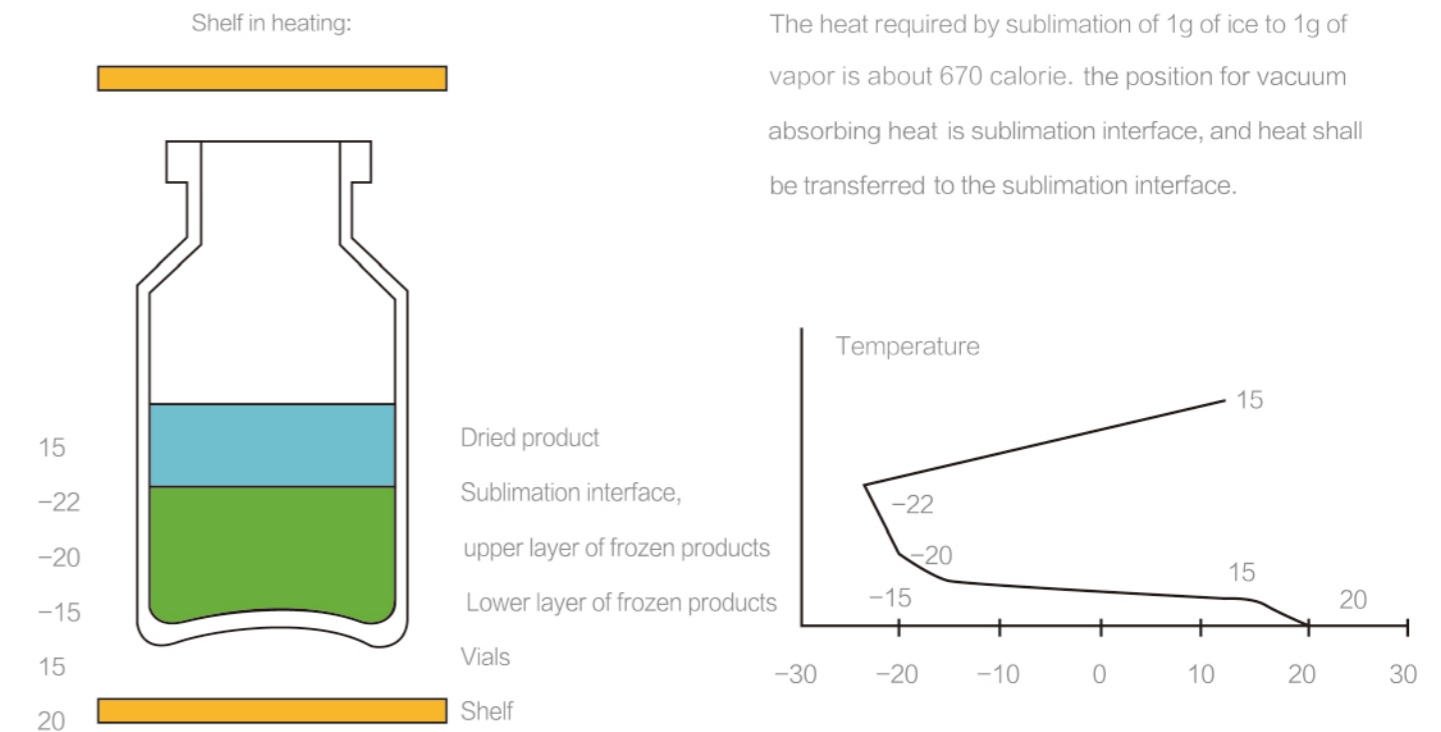


The vials at the edge are labelled as E. The percentage deviation of average sublimation amount of water in vials not at the edge (nE) from the value identified in the circle, and the average deviation of all vials at the edge is 15.0%.

The average deviation of all vials not at the edge is 0.11%.

Temperature control for products with no sensor

Because the freeze dryer equipped with automatic loading and unloading system cannot be placed temperature probe. AUSTAR adopts international advanced BTM technology to control product sublimation interface temperature precisely, and prevent drug products collapsing and melting. The control results are much better than traditional estimation of product temperature by means of the temperature of silicone oil on the shelf.



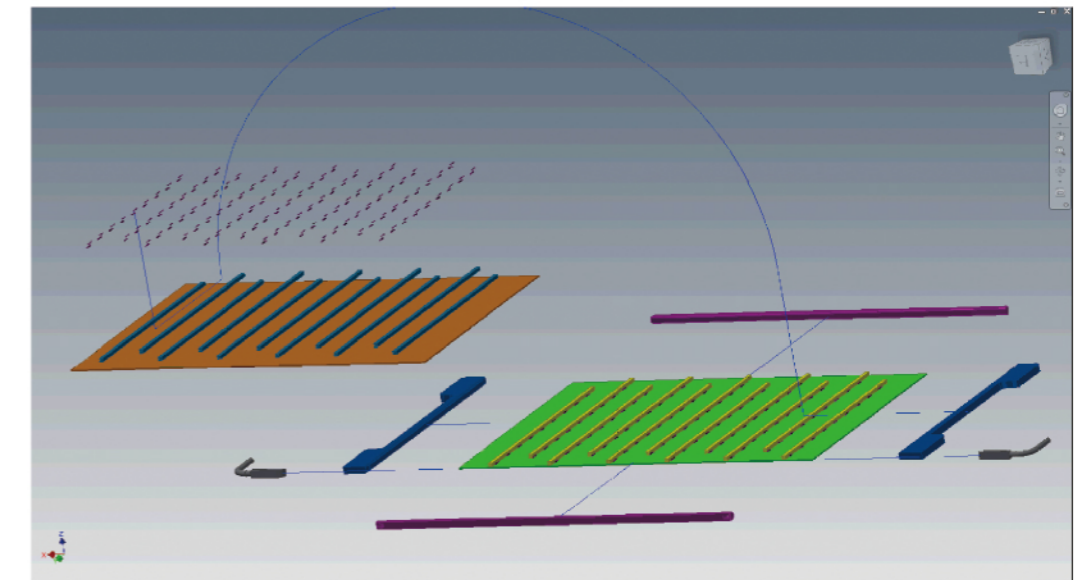
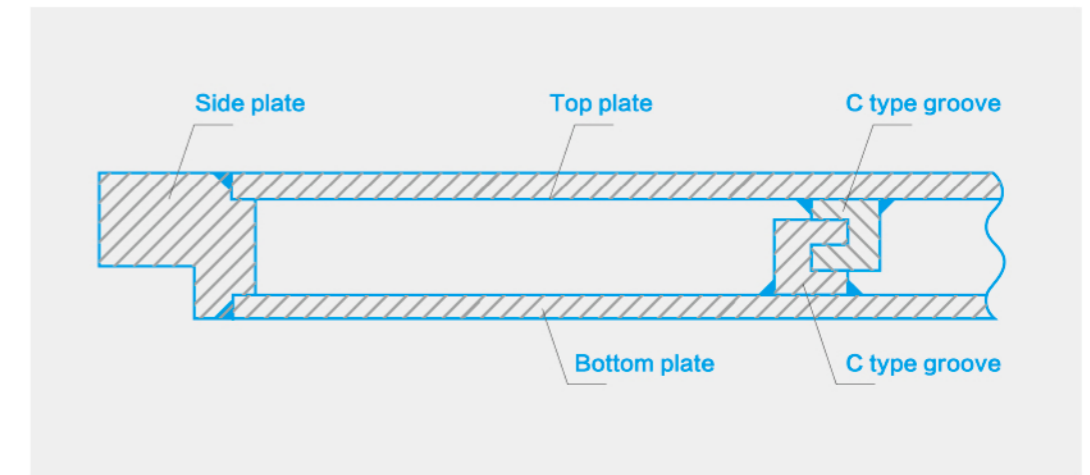
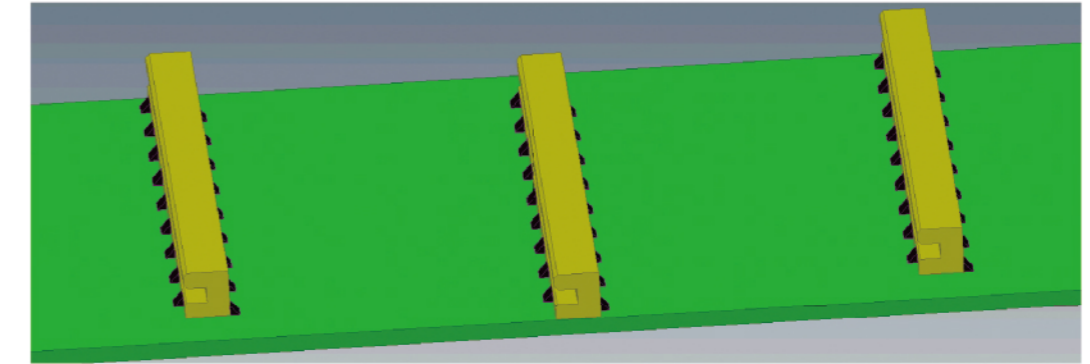
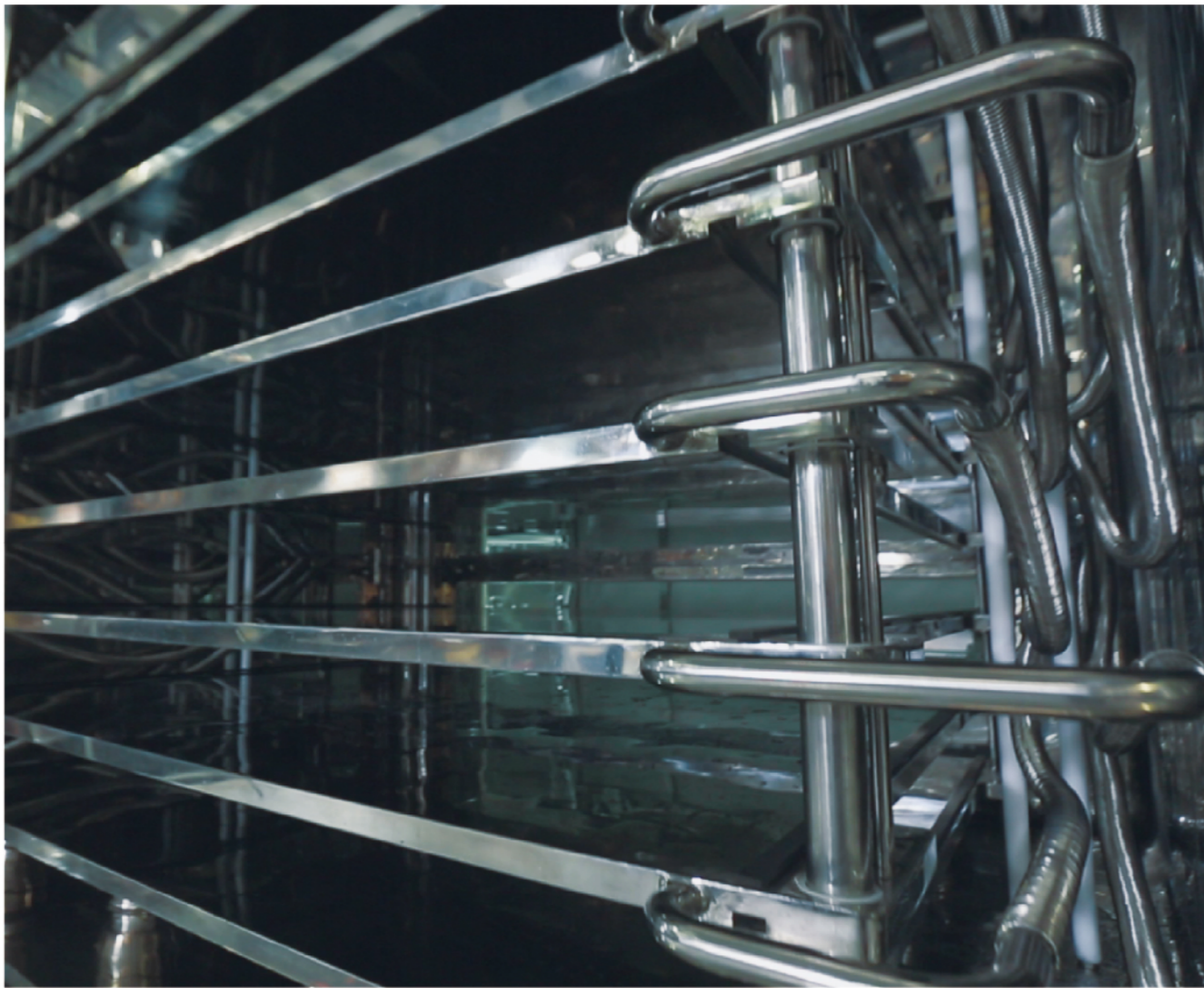
The heat required by sublimation of 1g of ice to 1g of vapor is about 670 calorie. the position for vacuum absorbing heat is sublimation interface, and heat shall be transferred to the sublimation interface.

Temperature difference between shelf and product during sublimation

Shelves Manufacturing

C type welding technology

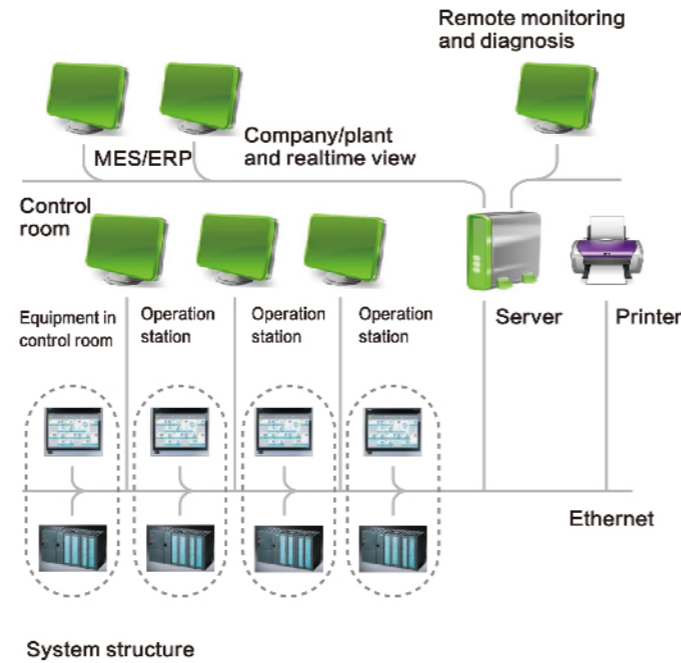
- 1 Welding and detection for different grades of pressure containers
- 2 Controllable welding technology is to avoid concentration of local heat stress, and no deformation is caused by release of heat stress at later phase
- 3 The welding is monitored to prevent non-uniform welding effectively, which results in oil leakage or shelf deformation



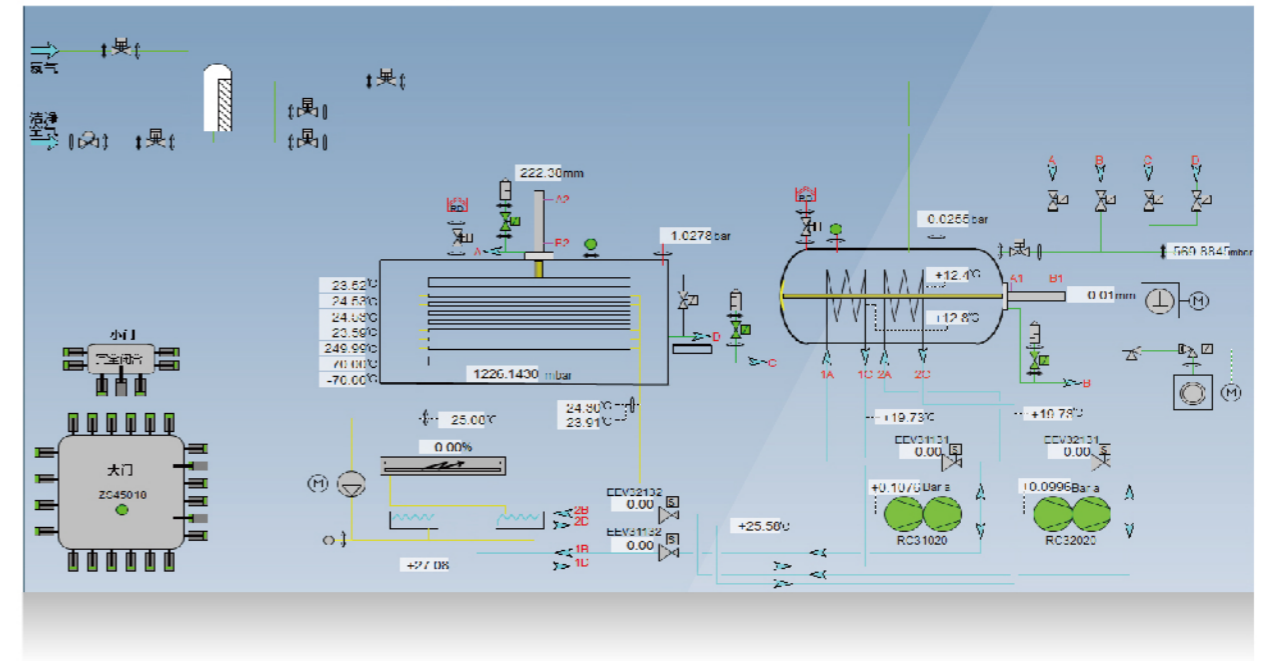
Intelligent Freeze-drying Control System

General

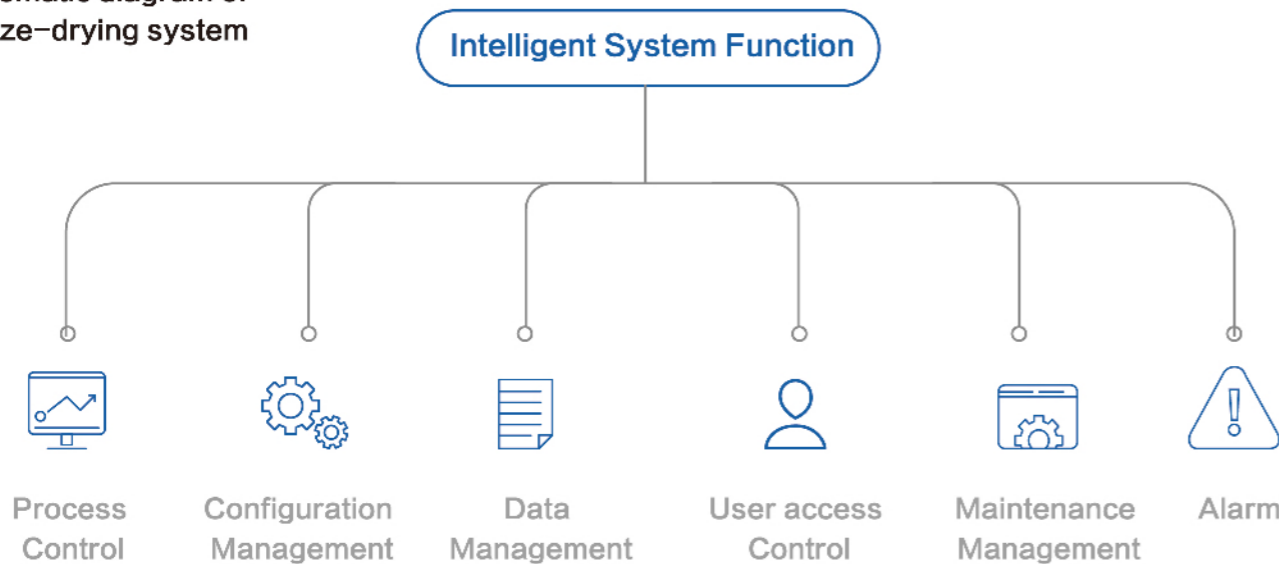
- AUSCON series software which specially services for pharmaceutical industry inherits the strong automation research capability of AUSTAR, and adopts international advanced control technology to ensure the stability of system control
- Core control software is developed on the basis of Siemens platform, and integrated strong automation and process capability of AUSTAR
- Advanced refrigeration and vacuum control technology to ensure the stability of process control
- AUSCON series software follows consistent advantage of computer validation of AUSTAR, designs on the basis of GAMP5 requirements completely, meets the requirements on electronic signature and electronic record in 21CFR PART11, and complies with increasingly strict requirements on computer validation
- Equipment is able to conduct interlocking and protection at the same time to prevent misoperation by the personnel
- The program is developed with the purpose of product protection, so as to protect product characters to the maximum in failure conditions.



Process Control



Schematic diagram of freeze-drying system



Formulation Management



Intelligent Freeze-drying Control System

Data Management

Intelligent maintenance reminder to facilitate equipment maintenance

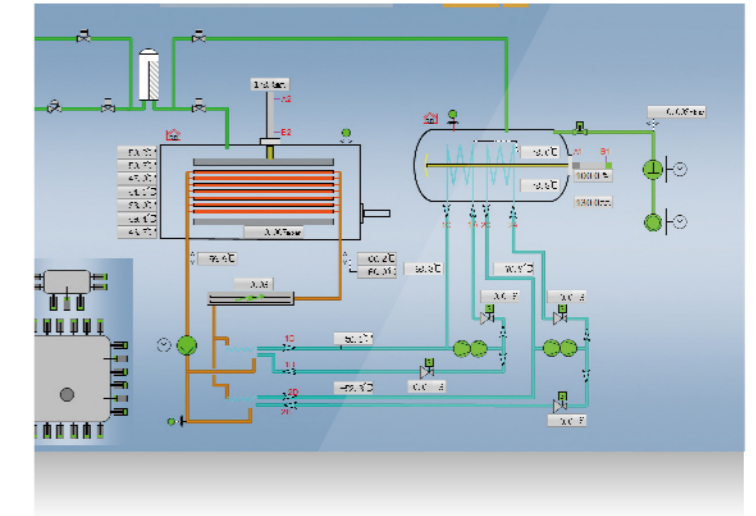
- Batch Data
- Operation Record
- Trend Data
- Alarm Record
- Export And Print Data
- Intelligent Maintenance Reminder

BPV10001	607.4	10000000	226	10000	0	0	1	0	0
BPV10002	508.0	10000000	1872	10000	0	0	0	0	0
SV10003	0.8	10000000	7	10000	0	0	0	0	0
SV10004	0.1	10000000	5	10000	0	0	0	0	0
SV10005	0.0	10000000	3	10000	0	0	0	0	0
SV10007	1024.0	10000000	16	10000	0	0	0	0	0
SV10008	1024.0	10000000	18	10000	0	0	0	0	0
SV10009	1024.0	10000000	35	10000	0	0	0	0	0
SV10051	0.0	10000000	1	10000	0	0	0	0	0
VP10010	711.5	10000000	254	10000	0	0	0	0	0
RVP10050	454.5	10000000	321	10000	0	0	0	0	0
DPV15001	13.0	10000000	61	10000	0	0	0	0	0
DPV15002	73.0	10000000	221	10000	0	0	0	0	0
DPV15004	67.2	10000000	132	10000	0	0	0	0	0
DPV15005	63.9	10000000	158	10000	0	0	0	0	0
DPV15006	71.5	10000000	181	10000	0	0	0	0	0
CV15007	5.0	10000000	94	10000	0	0	0	0	0
DPV15021	20.1	10000000	46	10000	0	0	0	0	0
DPV15022	26.1	10000000	45	10000	0	0	0	0	0
SV20010	328.3	10000000	168	10000	0	0	0	0	0
SV20013	361.0	10000000	123	10000	0	0	0	0	0
SV31010	405.0	10000000	101	10000	0	0	0	0	0
BEV31231	441.4	10000000	209	10000	0	0	0	0	0
BEV3132	435.0	10000000	85	10000	0	0	0	0	0
SV32091	465.0	10000000	157	10000	0	0	0	0	0
BEV32131	412.5	10000000	149	10000	0	0	0	0	0
BEV32132	434.2	10000000	67	10000	0	0	0	0	0
HC32020	403.0	10000000	211	10000	0	0	0	0	0
HC32020	405.7	10000000	121	10000	0	0	0	0	0

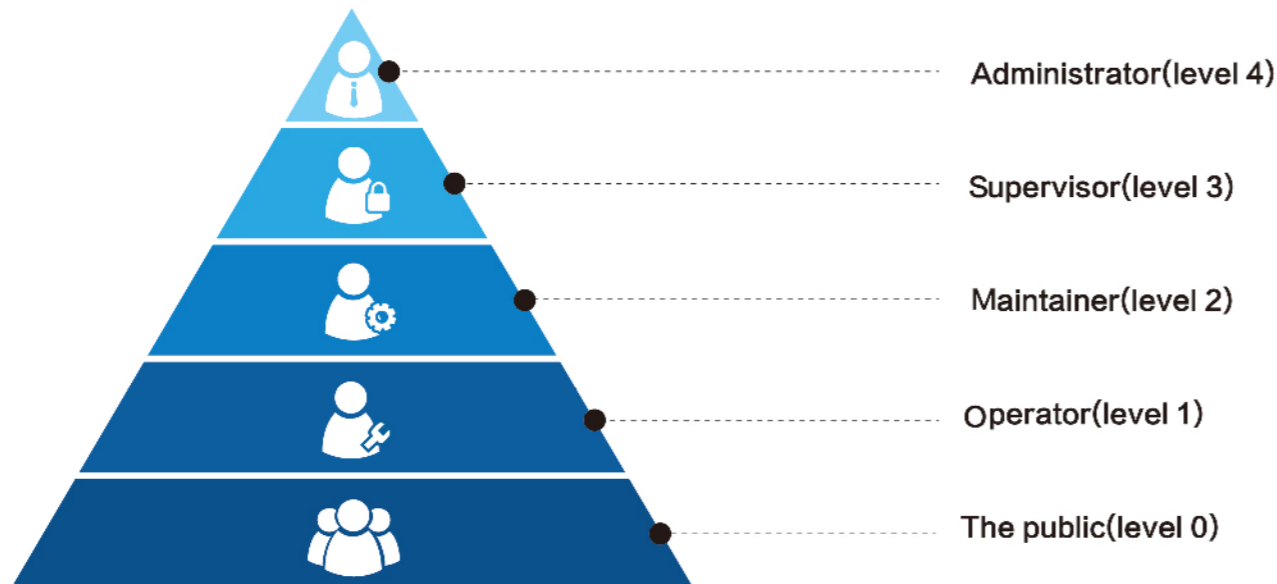
Maintenance Management

Intelligent test function conducts overall inspection for freeze dryer.

- Manual test for valve and pump
- Sensor test
- System integrity leak test
- Stopping bellows test
- Chamber-condenser isolating valve bellows test
- Discharging pushrod bellows test



User Access Control



Alarm System

1 Multi-level alarms

Level 1 alarm having impact on the product (vacuum is abnormal during freeze-drying process)

Level 2 alarm having no impact on the product, but to be verified by manual

Level 3 Reminding alarm

2 Intelligent EMAIL short message reminder (option)

Set critical alarm parameters, timely inform administrator, record and raise response speed, reduce quality risk.

3 Alarm verification

Password input to verify information Intelligent reminder about the actions/measures to be taken and possible reason

Product Description

AUSTAR freeze-drying system sterile isolator adopts physical and dynamic segregation to provide isolation protection for clean areas of different cleanliness grades. It provides excellent sterile isolation solutions for users by establishing barrier between operation area and personnel, supported by advanced material transfer technology and biological removal method.

AUSTAR freeze-drying system isolators include ORABS/CRABS/ISAOLATOR, etc. to provide the customer with all-round isolation services.



Highlights

1 High-standard isolation protection

AUSTAR isolators include ORABS, CRABS, ISOLATOR, etc., to meet the isolation requirements for grade A/B/C/D clean area in clean facilities. Meanwhile, ISOLATOR can meet the requirements of OEB5 drug isolation protection by the customer.

2 Sterile validation service

AUSTAR isolation system can provide the customer with relevant facilities and services such as matched VHP sterilization, HVAC, and sterile validation.

3 Precise environment control

AUSTAR isolation system can control different work units by several sets of air conditioners to make the control to internal environment of isolator more precise.

4 Protection of filter system

The isolator adopts internal return air filter system to avoid the back-end of return air duct being contaminated, and prolong the period for changing HEPA filter in plenum chamber by the customer.

5 Easy for cleaning

The decorative sheet of isolator adopts internal wiring, all interior angles of the chamber is designed with circular arc, it has elegant appearance and is easy for cleaning, it can reduce cleaning difficulty and shorten cleaning time.

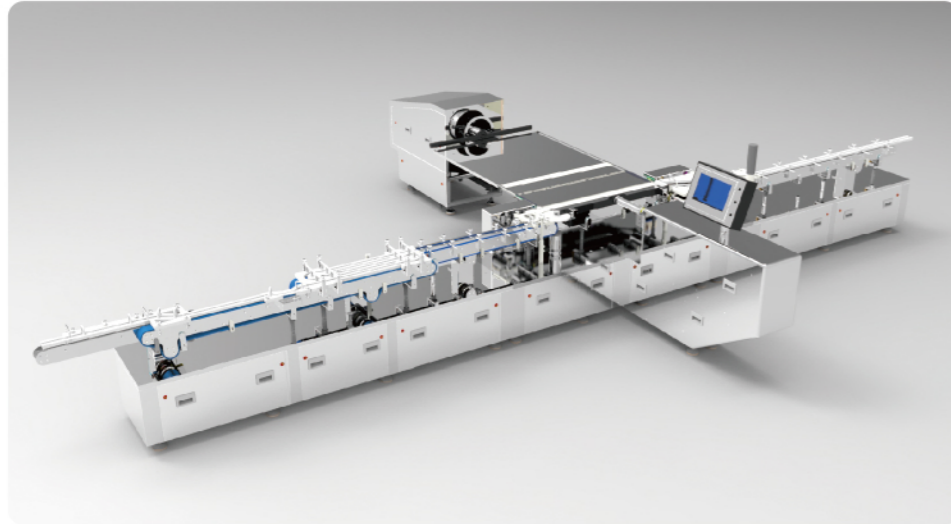
6 High sealing of cover plate

The cover plate of isolator has double sealing, the glass door lock is equipped with signal light and alarm functions, the areas with different differential pressures are separated by sealing lift door, and materials are transferred between isolator and outside through RTP to reduce the leakage probability and risk of contamination taken to products as far as possible.



Automatic Loading and Unloading System

Product Description



The automatic loading and unloading system can reduce the number of operators, and risk of contamination of personnel to products. It adopts modularized design and manufacturing, which is customized as per customer requirements.

Highlights

1 Fast accessible docking

Sterile filling line is docked with automatic loading and unloading system by slipping transfer system to realize the requirements for fast docking with filling machine of any brand at home and abroad

2 Compact design

Snakelike buffer transfer system can meet the requirements of manufacturing process, meanwhile, reduce the area of automatic loading and unloading system to the maximum in sterile plant

3 Loading with low temperature

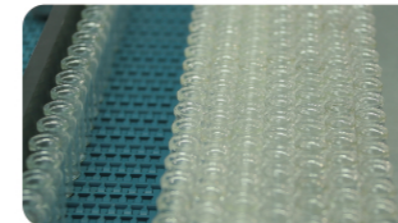
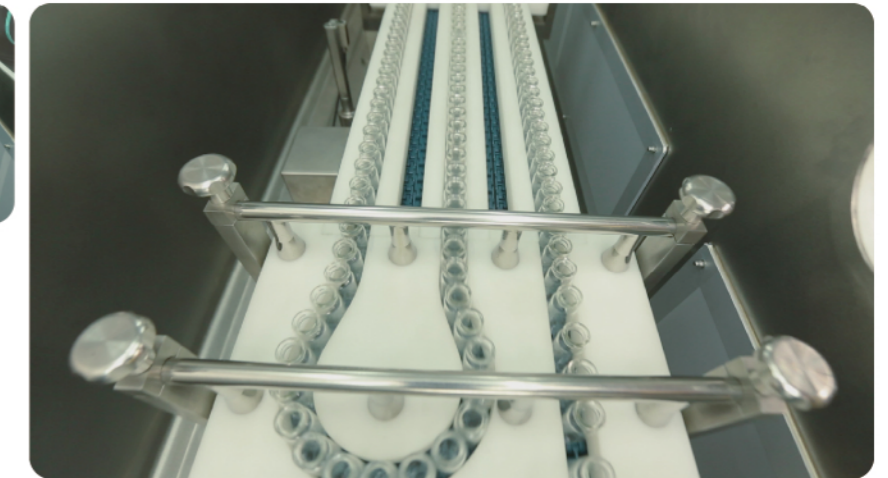
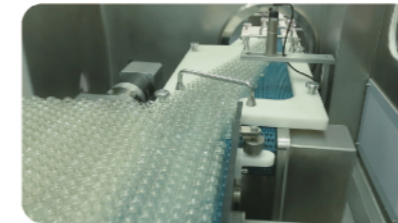
The loading system not only meets the requirements of routine loading manufacturing process, but also meets the requirements of loading manufacturing process at low temperature

4 High productivity

The unloading system adopts many kinds of unloading methods to meet the production requirements for single and multiple high speed capping machines.

5 High stability

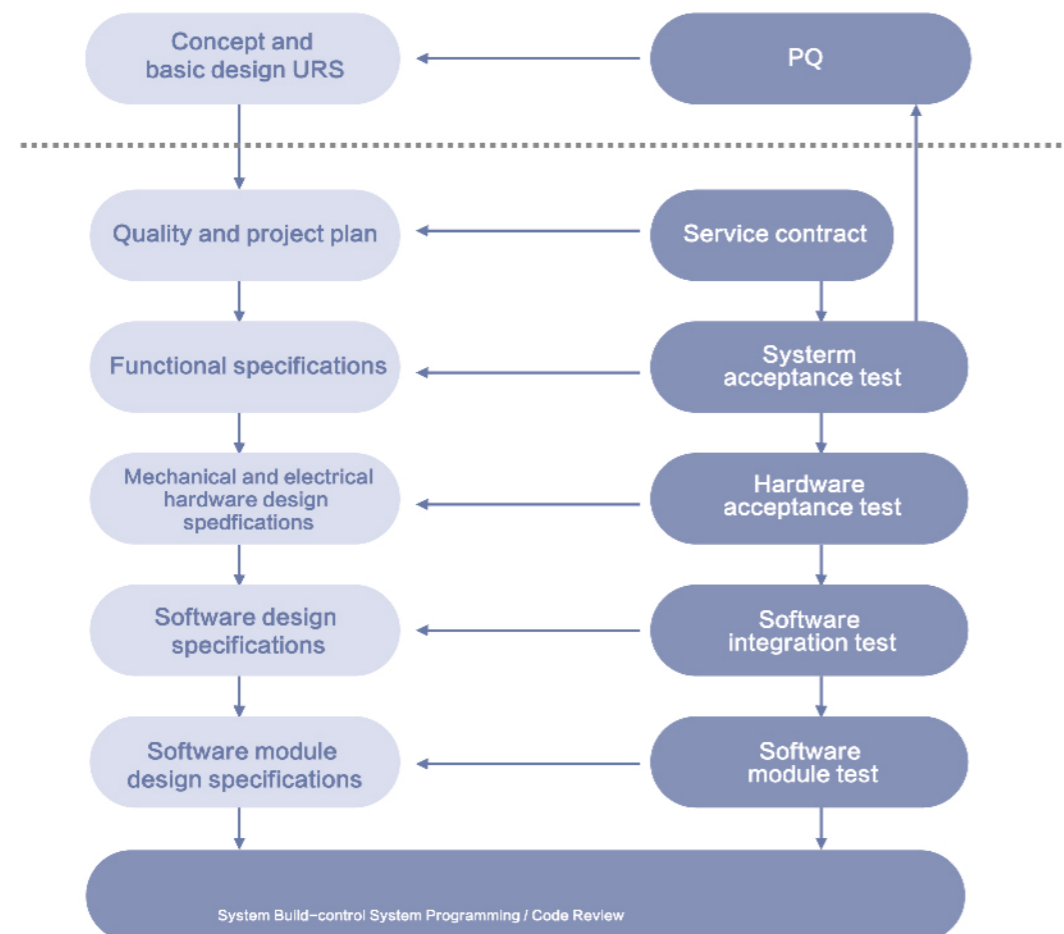
Driven by several servo motors + variable frequency motor, which have high stability, and can avoid risk caused by starting control



GAMP5

Control system is designed and tested according to the requirements of GAMP5.

- GXP expert team from home and abroad recognized by global pharmaceutical industry, and several senior international registration consultants.
- Professional GXP service experience from more than one hundred pharmaceutical enterprises
- Close cooperation with many foreign consulting agencies to possess industry resources within the worldwide scope
- Provide professional and comprehensive GXP compliance consulting services, which comply with the requirements of regulations such as FDA/EMA/CFDA/WHO, etc.



- Provide all-round validation service for the customer with validation plan throughout the equipment lifecycle
- Inherit consistent validation speciality of AUSTAR
- Rich validation experience on FDA projects provide reliable guarantee for documentation system



Successful experience on validation over years not only originates from the understanding on certification, but also originates from the meticulousity to validation execution.

Freeze-drying Process Optimization

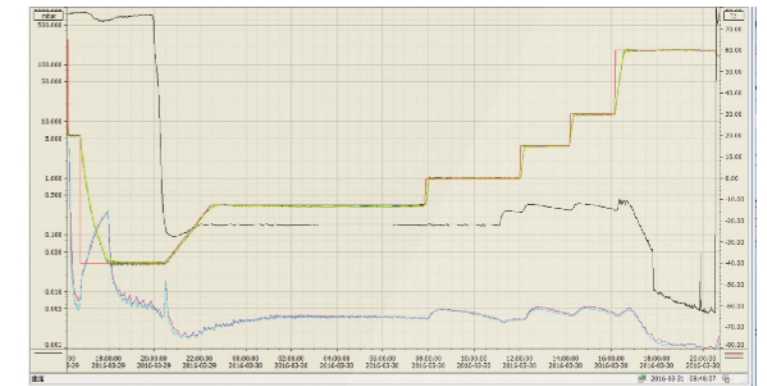
Development of freeze-drying process curve

- Advanced process research and development technology to assist in formulating more effective process curve based on drug properties
- Improve elegant appearance of the product, reduce costs and enhance productivity.
- Residual moisture test
- Validate the eutectic point by using DSC analyzer.
- Optimize vacuum and temperature by introducing international technology to avoid drug melting and collapsing.



Unacceptable phenomena

- Product spraying
- Product shrinkage and bulge
- No fixed shape
- Product not dried completely
- Non-uniform product color
- Product layering
- Unqualified water content
- Product vacuum breaking



After-sales Service

Training plan

High efficient,high quality and professional after-sales service team provides you with more professional after-sales service AUSTAR has an after-sales team of 50 persons,who have the after-sales service experience on imported freeze dryer for 20 years,they have constantly engaged in commissioning,maintenance,upgrade and renovation of imported freeze dryer over years.

Specific all-round training plan, including training for operator, equipment maintaining personnel, equipment management personnel and validation personnel. The owner can not only understand equipment and freeze-drying process comprehensively, but also improve the operation level, maintenance capacity of the whole team to bring long-term return for the enterprise.

Training plan

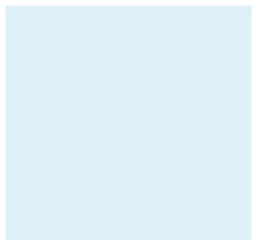
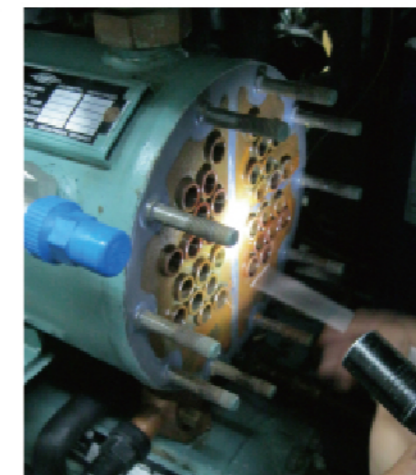
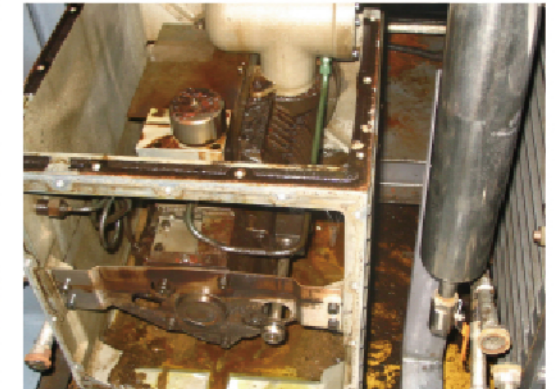
- Equipment basic structure and principle, operation and failure identification
- Periodic maintenance plan
- Troubleshooting



Preventive after-sales plan

Periodic maintenance and circuit inspection rules require to visit the customer regularly, and check equipment performance and customer use conditions so as to nip in the bud. The equipment files covering equipment lifecycle will bring more careful after-sales experience for you.

- Ensure the continuity and safety of equipment operation
- Prolong the equipment lifecycle
- Reduce the burden of routine equipment maintenance



AUSTAR Freeze Dryer Lectotype

Models	Shelf interdistance mm	Shelf specification (L x W x δ) mm			Number of shelves	Total area m ²	Condensation capacity Kg	Max. packing volume (approx.)		Total power Kw	Weight Kg	Cooling water flow m ³ /h	Dimension of unit (LxWxH) mm
								Φ 16;	Φ 22;				
AFD-0.5	100	450	300	20	4+1	0.54	10	Φ 16: 2200PCS	Φ 22: 1150PCS	6	880	air-cooled	1485*1132*750
AFD-1	(85 ~ 120)	600	450	20	4+1	1.08	20	Φ 16: 4340PCS	Φ 22: 2300PCS	15	2400	5	2600*1600*2600
AFD-2		900	600	24	4+1	2.16	40	Φ 16: 8830PCS	Φ 22: 4510PCS	25	4000	5	3560*2500*3220
AFD-5		1200	900	24	5+1	5.4	100	Φ 16: 22050PCS	Φ 22: 11250PCS	55	8500	6	5600*1900*3225
AFD-7.5		1200	900	24	7+1	7.5	150	Φ 16: 30800PCS	Φ 22: 15750PCS	65	9500	8	5600*2000*3800
AFD-10		1200	900	24	9+1	9.72	200	Φ 16: 45100PCS	Φ 22: 23400PCS	85	12000	13	4800*2650*4800
AFD-13		1200	1200	24	9+1	12.96	260	Φ 16: 58000PCS	Φ 22: 30100PCS	85	15000	13	7600*2500*4200
AFD-15		1200	1200	24	10+1	14.4	300	Φ 16: 64800PCS	Φ 22: 34560PCS	96	16200	15	7200*2650*4800
AFD-18		1500	1200	24	10+1	18	360	Φ 16: 81000PCS	Φ 22: 42400PCS	112	18400	13	8600*2800*4500
AFD-20		1500	1200	24	11+1	19.8	400	Φ 16: 80900PCS	Φ 22: 41300PCS	125	22800	24	8960*2700*5950
AFD-25		1500	1500	24	11+1	24.75	500	Φ 16: 110400PCS	Φ 22: 58300PCS	145	25600	15	9100*2800*5200
AFD-30		1800	1500	24	11+1	29.7	600	Φ 16: 130900PCS	Φ 22: 70300PCS	165	28200	18	9600*3200*5200
AFD-35		1800	1500	24	13+1	35.1	700	Φ 16: 154700PCS	Φ 22: 83100PCS	182	28800	25	9600*3200*5200
AFD-40		1800	1500	24	15+1	40.5	800	Φ 16: 178500PCS	Φ 22: 95800PCS	212	30000	35	10500*3200*5800
performance parameter	shelf temperature range		Shelf heating speed		Shelves temperature uniformity		Shelf cooling time		Stoppering force		Coiled temperature Min		
	-55°C ~ 80°C		1°C/min		± 1°C		20°C ~ -40°C ≤ 60min		0 ~ 0.15Mpa		≤ -75°C (R507)		
	Condenser cooling time		Evacuation time		Final vacuum		Leakage rate		Shelf flatness		Finish of shelves/maintance door		
	20°C ~ -40°C ≤ 30min		103mbar ~ 0.1mbar ≤ 30min		≤ 0.005mbar		≤ 1*10 ⁻² mbar · L/s		± 0.5mm/m		Ra ≤ 0.4 μ m		

OPTIONS:

- CIP
- SIP
- Screw compressor
- Piston compressor
- Dry vucuum pump
- Rotary vane vacuum pumps
- Automatic filter integrity test
- Volatile Solvents collector