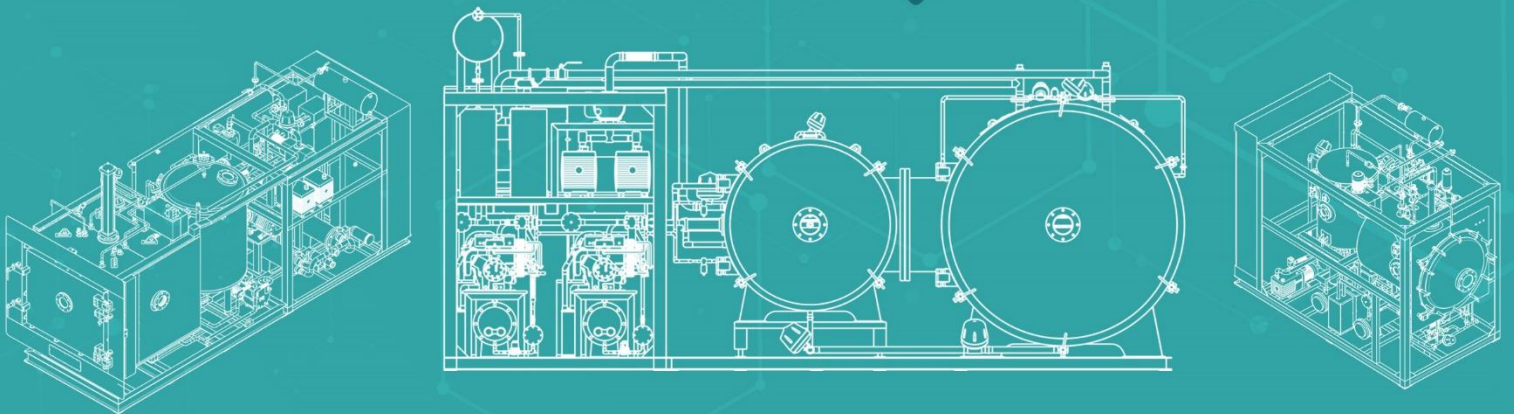
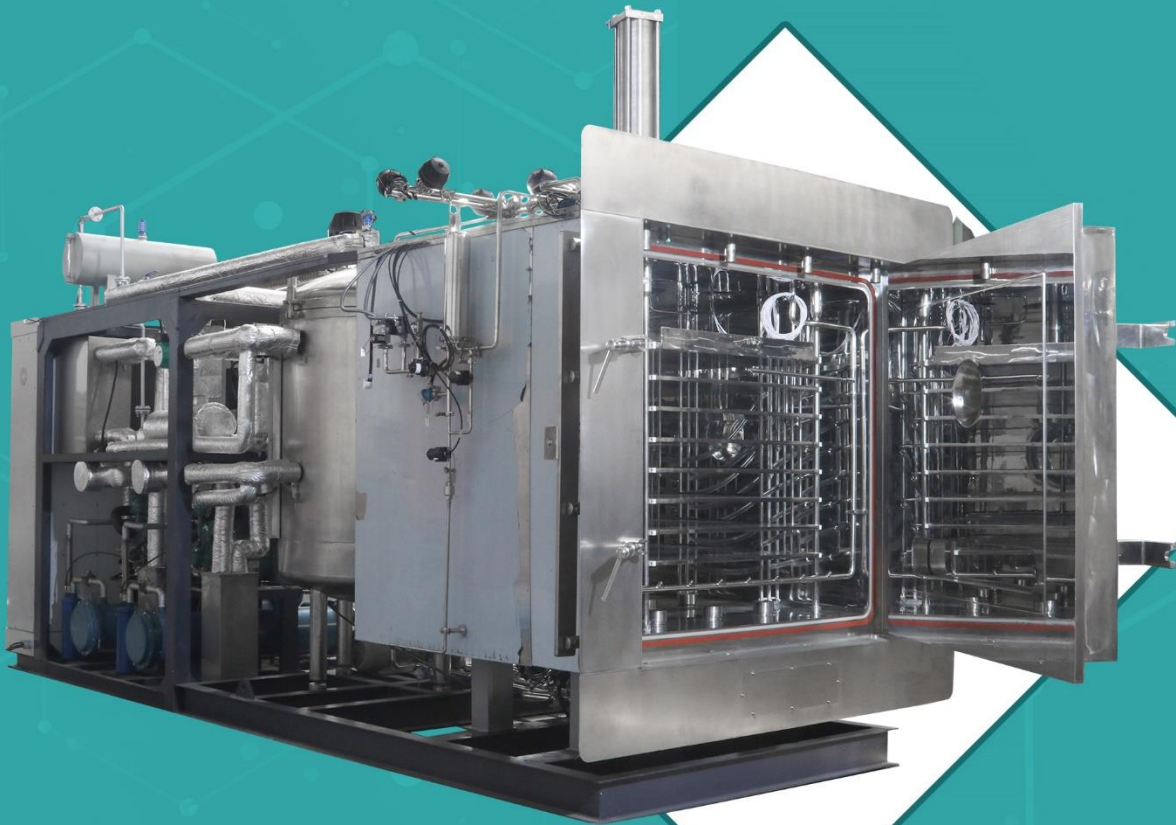




# Pharmaceutical Freeze Dryer Machines



**Parseh Freeze Dry**  
Made In Iran

**PARSEH**  
**FREEZE DRY**



**Pharmaceutical**  
**Freeze Dryer Machines**

# Freeze Dryer Machines

Takvin Azmayesh Parse company (Parseh Freeze Dryer) designs and manufactures pharmaceutical freezer dryers from half a square meter of shelf area to forty square meters of shelf area in the pharmaceutical & biotech industry and up to one hundred square meters of shelf area in the food industry.

In all subsystems of the freezer device, all the necessary indicators and parameters have been designed and implemented to create a capable and integrated control system. The quality of all components, subsystems and systems and the product is managed and controlled in an integrated process. In the whole process of supply to production and operation, maintaining and increasing the reliability of the product is very important. We consider our continuous effort in innovation and commitment to research and development as a key task and this is our biggest strategy and interest. Are you uncertain about what freeze dryer you should choose? Parse freeze dry provides pre-production capabilities from our Innovation Centre in university. This offers you the unique opportunity to test your application on our freeze dryers beforehand.

Freeze dryers designed and manufactured in Parse Freeze dry are generally divided into three categories:

Pharmaceutical freeze dryers:

PHS1(2 Type), PHS2 (2Type), PHS3 (4 Type), PHS4 (2 Type), PHS5 (3Type).Pilot

Biotechnology freeze dryers:

Bio12, Bio120, Bio240, Bio360, Bio600, Bio1000

Food freeze dryers Machine:

FD20, FD100, FD200, FD300, FD500, FD1000, FD2000

Pilot freeze dryers Machine :

PFD-S1, PFD-S2, PFD-S3, PFD-S4





## ◆ Main Chamber

The main chamber of the device is designed and made in the form of a cube or cylinder according to URS. All internal surfaces of the chamber, all fittings and valves, main door, pizza door, hydraulic jack bellows and nozzles are made of austenitic stainless steel SS316L. All internal surfaces of the chamber, all internal components and parts have been polished by mechanical polishing and electro polishing to a surface smoothness of less than 0.4 micromoles. This chamber is designed in a way that in addition to features such as easy access to internal components, cleaning and necessary services, it has the least unused space or the so-called dead space. The corners are roundly designed to be easily cleaned and a suitable slope towards the drain is considered. All design and construction steps are performed according to relevant standards such as ASME (Sec. VIII) for absolute vacuum pressure up to 2.5 bar Gage and the temperature of - 80°C to +150 °C. The requirements of complementary standards such as ASME BPE (with GMP requirements), API (with special pharmacological considerations) and 13408-5 ISO standard are also considered.

## ◆ Main Door

The main closure is a quick-opening type and the chamber can be accessed in a few seconds. For sealing the door, O-ring with double-sided silicone material is used to withstand internal and external pressure. A sight valve with sufficient light is installed on the main door from which the operator can observe the drying process of the product from this part. The automatic clamping system is intended for large chambers for the sake of security in SIP cycle.



# Freeze Dryer Machines

## ◆ Shelf Assembly & Heat Exchange System

The heat exchange system includes shelves, silicone oil circulation system and heater. Cooling and heating of the shelves is done by circulating silicone oil in them and exchanging refrigeration and heat in heat exchanger plate and also the heater. The Silicone oil rotates in the circuit by a canned pump. The body and blades of the pump are made of 304L or 316L steel which reduces sensitivity to temperature changes in the pump. The Shelves have temperature uniformity per square meter and their non-smoothness is less than 1mm per square meter. The smoothness of the shelf surface is less than 0.6 um to ensure that they are thoroughly washed and sterilized.

The double PT100 sensor is used to control the oil temperature. The drying operation of the products in the freeze dryers is done in bulk (on a tray) or in vials. Therefore, the shelving system is made fixed or movable. In pharmaceutical devices where the shelves are movable, and have a stoppering system, the vials are closed automatically inside the vacuum chamber. The stoppering system is hydraulic and the shelves move from top to bottom. The jack moves inside the main chamber and in order to follow GMP requirements, a steel bellows covers the jack bar. Due to the fact that the stoppering force must be controllable, a hydraulic motor controller by PID method has been used.



## ◆ Refrigeration System

Refrigeration system design is based on standards and customer URS requirements. Minimum shelf and condenser temperature, shelf and condenser cooling rate, optimum superheat rate and sub-refrigerant frig cooling are considered to protect compressors and optimal performance in electrical energy consumption. Electric expansion valves have been used to better control the temperature of the shelf and the steam trap.

## ◆ The design objectives of this system include the following:

- Reliable operation of the refrigeration system at variable frigorific loads and extended operation of drying cycle.
- Minimum shelf temperature
- Cooling rates higher than 1°C/min of shelves
- Steam condenser temperature up to -80°C/min
- Suitable uniformity of temperature in steam condenser
- Easy system maintenance





# Freeze Dryer Machines

## ◆ Vacuum System

The arrangement and type of vacuum pumps, the location and size of the main tank and condenser connection, the vacuum piping, the isolated valves of the pump and condenser, the O-rings and the seals are selected in such a way that the vacuum system can achieve the following goals:

- Vacuum construction up to 0.13mbar, almost 20 mins.
- The final chamber vacuum is less than 0.01mbar.
- The leakage rate of the whole device is less than 0.02mbar. L/sec.
- Preventing the steam entering into the vacuum pumps.
- Easy device maintenance.

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## ◆ Ice Condenser

In this device, the condenser is of a coil type, which the company has gained good experience in designing and manufacturing them. In designing an ice condenser, creating the actual capacity for the condenser should be considered. In fact, this refers to the uniformity in forms of the ice on the surface of the condenser. Ice uniformity on condenser surfaces is based on some criteria such as proper temperature uniformity in coils, minimum temperature fluctuation in condenser, size and position of steam entrance from main chamber to the condenser chamber, parallelism in steam flow and coils, uniform pressure distribution of condenser tank. On the other hand, the condenser chamber should be designed in such a way that it is possible to defrost, wash and remove the ice (melted) completely.

The entire exterior surface of the chamber is covered with insulation of suitable thickness and covered with steel sheet.

The condenser chamber is separated from the main chamber by a butterfly valve or mushroom valve.

The condenser chamber can be placed behind, next to or below the main chamber according to the customer's suggestion.





# Freeze Dryer Machines

## ◆ Control System & Instrumentation

The main tasks of the freezer dryer control system include receiving physical quantities from instrumentation equipment (shelf temperature sensors, product, pressure and vacuum temperature, flow and surface switches), comparing these quantities with input data and executing commands by observing Interlocks. The software of control system, protects the product and monitors the running freeze drying process. This system also maintains the reliability of the device's hardware performance. Integration and centralization on refrigeration system control (compressor operation, superheat control in operators, etc.) and heat transfer system (accurate implementation of temperature gradients and temperature stabilization in shelves) by installing temperature and pressure sensors on the components of this system are provided.

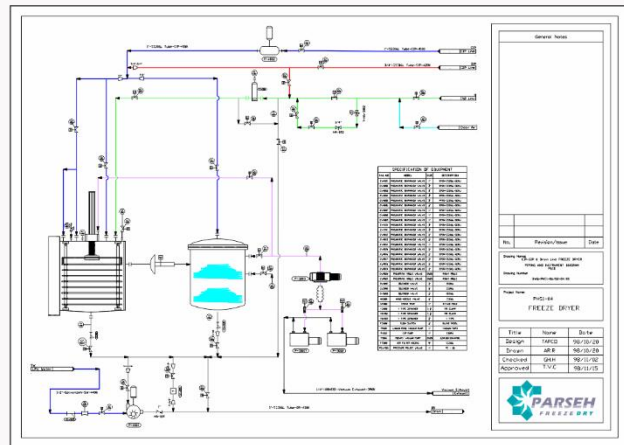
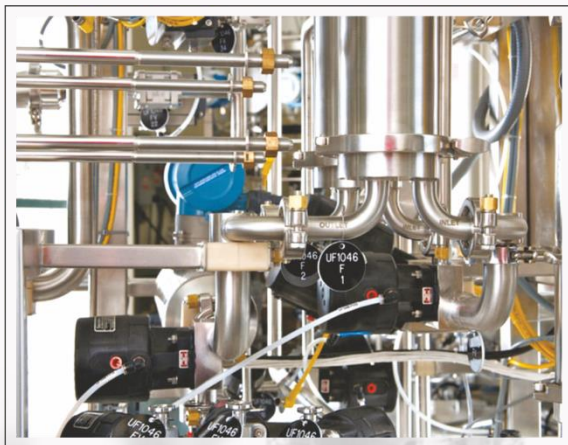
## ◆ Control system features

- Ability to define and save recipes.
- Ability to control and monitor from the outside (optional).
- Collect and store process data and performance data of other device subsystems.
- A menu display of status on all screens.
- Control system software on Windows CE.
- Implementation performance testing of the device through System Test.
- APLC/PC/HMI platform in the context of industrial Internet network.
- Implementation of Title 21CFR Part 11 requirements.
- Synoptic display to present the schematic function of the device.
- SCADA structure-based control system software.
- Implementation of freeze drying cycle in manual, semi-automatic and fully automatic modes.
- Ability to perform automatic static leakage testing of the device.
- Perform Pressure Rise test to detect the end of the initial drying stage.
- Alarm display, device failure status and the ability to save display alarms in the history alarm.
- Ability to automatically run CIP, SIP and Defrost cycles and report the performance of the cycle.



## ◆ CIP & SIP

This equipment has the ability to perform SIP and CIP operations automatically and intelligently. The design of the components is optimized and there are no corners or cavities that cause water droplets from the condensation to collect. Temperature and pressure control sensors monitor the situation during the process constantly. The chamber of the device is equipped with an automatic steam pressure relief valve, to protect the chamber against the accumulation of pressure. Inlet port nozzles expel air from inside of the chamber and steam fills the entire chamber space. Sterilization is performed by pure steam and during this operation, the door is automatically locked by pneumatic clamps. A liquid ring pump is used to drain the water remaining after sterilization. Also, suitable insulations have been used to maintain the chamber temperature. Sterilization is performed by ISO 513408 and ASME BPE requirements and other standards provided by the employer.



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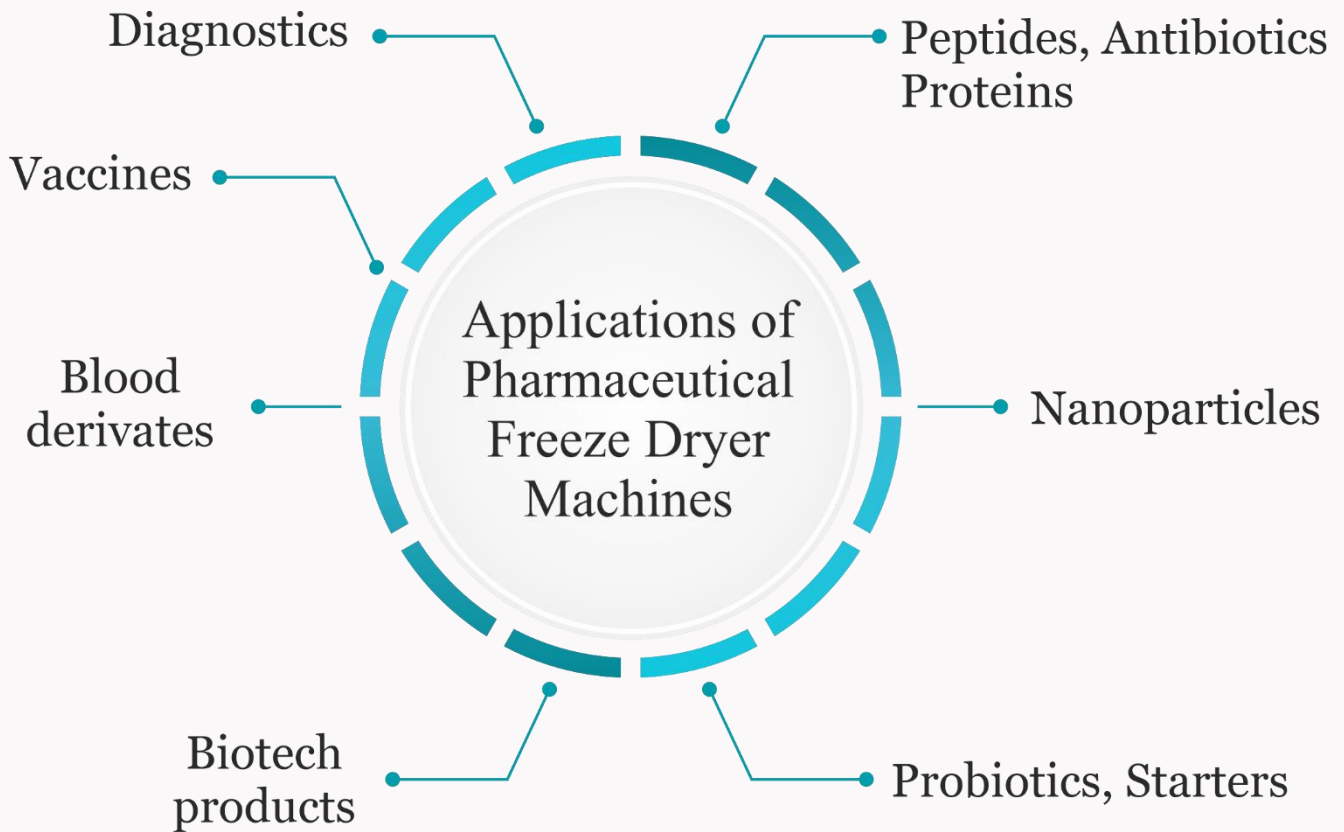
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# Freeze Dryer Machines





	PHS1		PHS2		PHS3			
All of Materials	SS316L							
Surface Finish	Less than 0.4 $\mu\text{m}$ (Mechanical & Electro Polishing)							
Type of Main Chamber	Cylindrical		Rectangular/ Cylindrical					
Type of Ice Chamber	Vertical Cylinder							
Number of Shelves	4+1	7+1	4+1	7+1	7+1	9+1	11+1	13+1
Shelf Dimension	420×650 mm		660×990 mm		930×1240 mm			
Useable Sublimation Area	1m <sup>2</sup>	1.9m <sup>2</sup>	2.6m <sup>2</sup>	4.6m <sup>2</sup>	8m <sup>2</sup>	10.4 m <sup>2</sup>	12.6m <sup>2</sup>	15m <sup>2</sup>
Distance Between Shelves	60 mm up to 120 mm (user specification)							
Shelf Temperature	-50°C to +70°C							
Shelf Temperatures Uniformity	±1°C							
Shelf Flatness	±0.5 mm/m							
Shelves Cooling Rate	+20°C to - 40°C less than 60 min ( $\geq 1^{\circ}\text{C}/\text{min}$ )							
Shelves Heating Rate	-40°C to + 20°C less than 60 min ( $\geq 1^{\circ}\text{C}/\text{min}$ )							
Ice Condenser Capacity	15kg	30kg	45kg	70kg	120kg	150kg	200kg	225kg
Ultimate Ice Condenser Temperature	-75°C							
Refrigeration Cycle Type	2 Stage Compressors, Electronics EXV, Water Cooled Condensers							
Vacuum Range	Less than 0.01mbar							
Vacuum Leak Rate	0.02 mbar. L/sec.							
Evacuation Time	Atm. to 0.13mbar Less than 20 min							
Chamber-Condenser Isolation Valve	Mirror Finished Mushroom / Butterfly valve							
Control of Machine	PLC& HMI Siemens, SCADA WinCC, Base on 21CFR Part11							
Pizza Door	-		Available					
Stoppering System	Available (Hydraulic Up to Down with SS316L Bellows Cover)							
CIP	Available							
SIP	Available							
Defrost Method	Hot Steam/Water							
GMP Documentation	Based on User Requirements							



# Freeze Dryer Machines

	PHS4		PHS5		
All of Materials	SS316L				
Surface Finish	Less than 0.4 $\mu\text{m}$ (Mechanical & Electro Polishing)				
Type of Main Chamber	Rectangular/ Cylindrical				
Type of Ice Chamber	Vertical Cylinder				
Number of Shelves	13+1	15+1	20+2	25+2	30+2
Shelf Dimension	1200×1200 mm				
Useable Sublimation Area	18.7 $\text{m}^2$	21.6 $\text{m}^2$	28.8 $\text{m}^2$	34.5 $\text{m}^2$	43.2 $\text{m}^2$
Distance Between Shelves	60 mm up to 120 mm (user specification)		60 mm		
Shelf Temperature	-50°C to +70°C				
Shelf Temperatures Uniformity	$\pm 1^\circ\text{C}$				
Shelf Flatness	$\pm 0.5 \text{ mm/m}$				
Shelves Cooling Rate	+20°C to - 40°C less than 60 min ( $\geq 1^\circ\text{C}/\text{min}$ )				
Shelves Heating Rate	-40°C to + 20°C less than 60 min ( $\geq 1^\circ\text{C}/\text{min}$ )				
Ice Condenser Capacity	300 kg	350 kg	450 kg	520 kg	650 kg
Ultimate Ice Condenser Temperature	-75°C				
Refrigeration Cycle Type	2 Stage Compressors, Electronics EXV, Water Cooled Condensers				
Vacuum Range	Less than 0.01mbar				
Vacuum Leak Rate	0.02 mbar. L/sec.				
Evacuation Time	Atm. to 0.13mbar Less than 20 min				
Chamber-Condenser Isolation Valve	Mirror Finished Mushroom / Butterfly valve				
Control of Machine	PLC& HMI Siemens, SCADA WinCC, Base on 21CFR Part11				
Pizza Door	Available		-		
Stoppering System	Available		-		
CIP	Available				
SIP	Available				
Defrost Method	Hot Steam/Water				
GMP Documentation	Based on User Requirements				



PILOT FREEZE DRYER MACHINE (PFD SERIES)				
	PFD-S1	PFD-S2	PFD-S3	PFD-S4
Overall Dimensions (m)	1.2W×1.2D×1.6H		1.4W×1.4D×1.6H	
Machine Frame and Cover	St 37-Epoxy Coated for Machinery Frame and SS304 for Machine Cover			
Materials of (Chambers, shelves & Ice Condenser)	SS 316L/SS 304L (Based on Request)			
Surface Finish	Less than 0.6µm			
Type of Main Chamber	Horizontal Cylinder			
Type of Ice Chamber	Ice Coils in main Chamber			Vertical Cylinder
Number of Shelves	3+1			
Shelf Dimension	305×550 (mm)			
Useable Sublimation Area	0.5 m <sup>2</sup>			
Distance Between Shelves	45 mm			100 mm
Shelf Temperature	Ambient ~ +60°C	-30°C~ +60°C	-50°C~ +70°C	-50°C ~ +70°C
Shelf Temperatures Uniformity	±1°C			
Shelf Flatness	±0.5 mm/m			
Ice Condenser Capacity	10kg			
Ultimate Ice Condenser Temperature	-50°C		-75°C	
Refrigeration Cycle Type	Hermetic Compressors, Electronics EXV/TEXV, Water Cooled Condensers			
Vacuum Range	0.01mbar			
Vacuum Leak Rate	0.02 mbar.L/sec.			
Evacuation Time	Atm. to 0.13mbar Less than 20 min			
Chamber-Condenser Isolation Valve	Not Applicable			Mushroom Valve
Control of Machine	PLC&HMI			
Stoppering System	Not Applicable			Up to Down
Manifold for Ampules	Option			
Defrost Method	Manual			Automatic by Hot Water
GMP Documentation	Based on User Requirements			



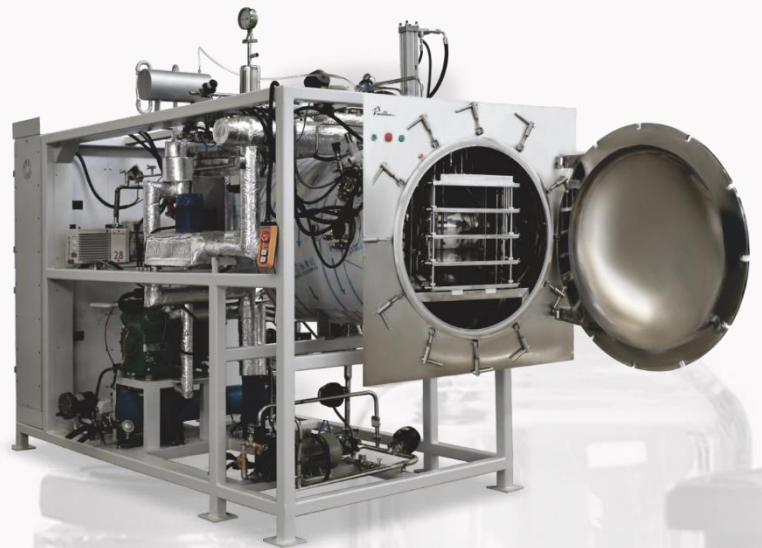
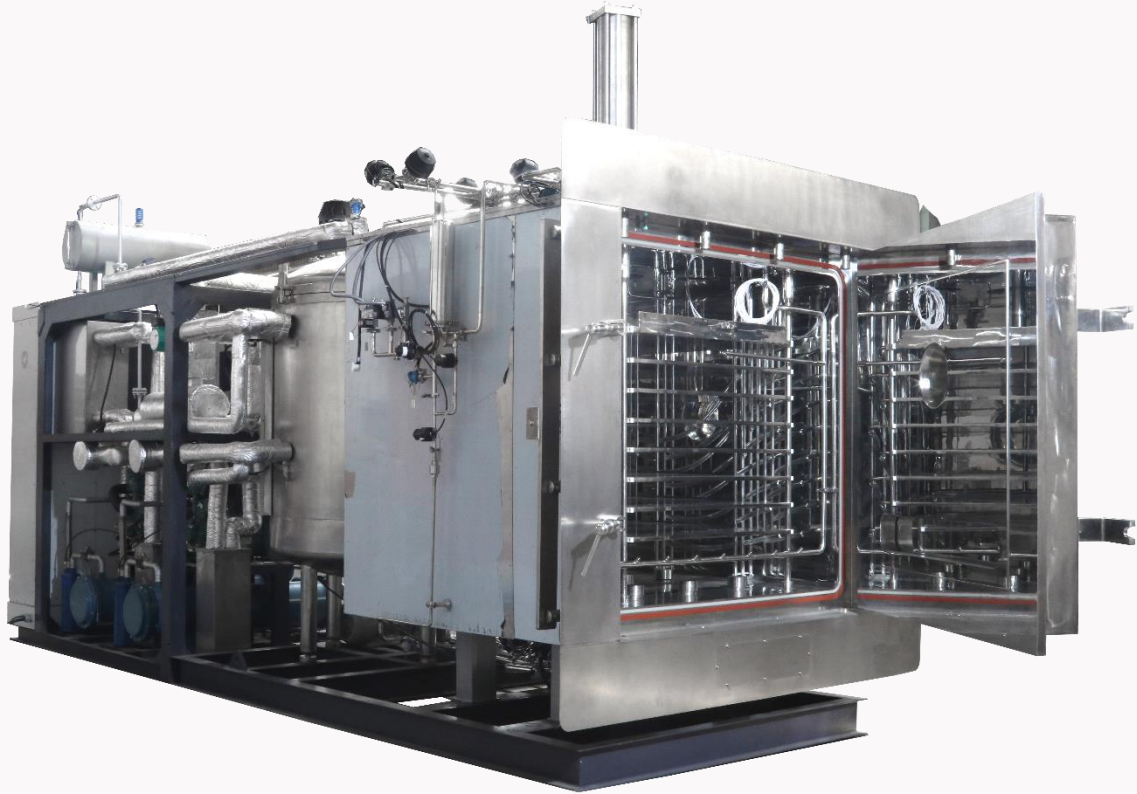


# Freeze Dryer Machines

Freeze Dryer Machines	Food Freeze Dryer (Conductive Shelves)				
	FD20	FD50	FD100	FD200	FD300
(Approximate Dimensions)	1.2W × 1.6H × 1.6L (m)	1.5W × 2.7H × 2L (m)	2W × 2.7H × 3.5L (m)	2W × 5L × 2.7H	4.5W × 3.2H × 4.5L (m)
(Chamber Materials)	AISI 304 Stainless Steel				
(Selves Materials)	AISI 304 Stainless Steel				
(Ice Condenser Coils Material)	AISI 304 Stainless Steel				
(Number of Shelves )	5+1	7+1	8+1	9+1	24+2
(Shelf Dimension)	390×1030	585×1220	1200×1200mm	1000×2400mm	1200×1200mm
(Shelf Spacing)	45mm				
(Total Useable Sublimation Area)	2 m <sup>2</sup>	5 m <sup>2</sup>	11.5 m <sup>2</sup>	21.6 m <sup>2</sup>	34.5 m <sup>2</sup>
(Shelf Temperature)	-45°C ~ +70 C				
(Product Freezing Method)	Silicone Oil /In Place				
(Ice Condenser Capacity)	24kg/Batch	60kg/Batch	120kg/Batch	240kg/Batch	360kg/Batch
(Final Ice Condenser Temperature)	-70°C				
(Refrigeration Cycle Type )	2 Stage Compressors, Electronics EXV, Water Cooled Condensers/ Air Cooled (Option)				
(Ultimate Pressure in Chamber)	0.02mbar				
( Chamber Vacuum Rate)	Atm. to 0.5 mbar ≤ 30min				
(Control of Machine)	PLC&HMI				
(Power Requirement)	6 KW, 380V, 3Ph,50Hz	18 KW,380V,3Ph,50Hz	24KW,380V,3Ph,50Hz	34KW,380V,3Ph,50Hz	54KW,380V,3Ph,50Hz
(Defrost System)	By Hot Water/Automatic (Option)				
(Approximate Weight)	850kg	2200kg	4200kg	6500kg	9500kg

Freeze Dryer Machines	Food Freeze Dryer (Conductive Shelves)			
	FD300	FD500	FD1000	FD2000
(Approximate Dimensions)	2.5W × 4H × 5L (m)	5W × 4H × 6L (m)	5W × 4H × 12L (m)	6W × 4H × 16L
(Chamber Materials)	AISI 304 Stainless Steel			
(Selves Materials)	6063 AL (Anodize Surface)			
(Ice Condenser Coils Material)	AISI 304 Stainless Steel			
(Number of Shelves )	10+1	13+1	13+1	17+1
(Shelf Dimension)	2600×1200	3400×1200	6800×1200mm	10000×1200mm
(Shelf Spacing)	90mm			
(Total Useable Sublimation Area)	31.2 m <sup>2</sup>	53 m <sup>2</sup>	106 m <sup>2</sup>	204 m <sup>2</sup>
(Shelf Temperature)	Ambient ~ +110°C			
(Product Freezing Method)	Quick Freezing Room			
(Ice Condenser Capacity)	375kg/Batch	625kg/Batch	1250kg/Batch	2500kg/Batch
(Final Ice Condenser Temperature)	-50°C			
(Refrigeration Cycle Type )	Screw Compressors, Electronics EXV, Water Cooled Condensers/ Air Cooled (Option)			
(Ultimate Pressure in Chamber)	0.1mbar (10Pa)			
( Chamber Vacuum Rate)	Atm. to 1mbar ≤ 30min			
(Control of Machine)	PLC&HMI			
(Power Requirement)	48 KW, 380V, 3Ph,50Hz	96 KW,380V,3Ph,50Hz	145 KW,380V,3Ph,50Hz	220 KW,380V,3Ph,50Hz
(Defrost System)	By Hot Water/Automatic (Option)			
(Approximate Weight)	9500kg	12000kg	18000kg	34000kg





# Freeze Dryer Machines

## ◆ Some of the competitive features and advantages of Takvin Azmayesh Parseh company:

- URS-based design and the possibility of changing the design based on the specific requirements of customers.
- Provide consultations on selecting and technical specifications of the product based on the type and device usage.
- Warranty and after-sales service, full support and prompt response in the shortest possible time to solve customer problems.
- Provide complete quality documentation in accordance with URS as well as surveillance requirements, develop complete maintenance and commissioning instructions.
- Possibility to visit the production line and observe related devices that have been used for previous customers.
- Accurate and professional training in operation and maintenance of the device at the startup time.
- Using the latest technologies in different subsystems of the device (refrigeration system, vacuum, heat transfer, control and instrumentation).
- Provide process and technical consultation to customers who haven't had industrial experience using the device.
- Possibility of conducting research tests in the field of edible products.
- upgrading outdated and used freeze dryers based on the latest requirements or customer's needs.





## ◆ Documentation

User and safety instructions

Maintenance instructions

Details of mechanical and locational charts

Process plans (P&ID)

Electrical charts, instrumentation and control

Material test reports

Documents of Welding qualification and inspection report

Calibration documents for control and measurement equipment (temperature, pressure, etc.)

Documents related to standard parts and equipment installed on the machines.

## ◆ QUALIFICATION AND VALIDATION

According to the customer's demands, the details of the certification / validation tests as well as the results obtained are performed within the framework of the specified protocols.

Facilities and equipment qualification is accomplished based on the type and requirements of the project. The following documents are also provided to customers and at the beginning of the project, certification protocols are prepared and implemented based on the project process:

- DQ (Design Qualification)
- IQ (Installation Qualification)
- OQ (Operational Qualification)
- PQ (Performance Qualification)



# Freeze Dryer Machines





Some of our customers





# Parse Freeze Dryers

## For The Pharma & Biotech Industry

Takvin Azmayesh Parseh Company Parseh Freeze Dryer) is the only designer and manufacturer of advanced pharmaceutical industrial Freeze Dryers in the Middle East and West Asia region.

The company designs and manufactures pharmaceutical freezer dryers from half a square meter of shelf area to forty square meters of shelf area in the pharmaceutical industry and up to one hundred square meters of shelf area in the food industry. Parseh Freezer Dryer Company has been designing and producing all kinds of advanced freezer dryers since 2009 and with the cooperation of hundreds of experts in design and technology of advanced systems of condensers, vacuum tanks, refrigeration, heat transfer, CIP & SIP, Stoppering, control and instrumentation, Develops

The freeze dryers are design and manufactured according to EUGMP guidelines and FDA recommendations (US FDA 21CFR PART 11) and European Conformity CE, under ISO 9001 Quality Assurance System. We have one of the most experienced teams in the industry. That guarantees that your project will meet your expectations both in quality and on-time delivery of the project.

At the time of delivery of the device according to customer needs, equipment qualification and software qualification certification tests are performed within the specified protocols, as well as DQ, IQ, OQ and PQ and instructions for use and maintenance of the device are provided to customers.

Cooperation with customers from the definition and start of the project to safe and sustainable operation is one of our main tasks.

Our goal is to create complete confidence and meet the quantitative and qualitative demands of customers based on the latest requirements and achievements of technology and innovation.

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