



# Pilot Freeze Dryer Machine

## PFD-S3 Model

*In The Name of God*

### 1) Over View:

TAPCO freeze dryer machines are made based on the latest technologies in the world. All subsystems in our FD machines conform to the relevant standards and the quality of these machines can be demonstrated in FAT and SAT tests.

#### ✓ **Chambers**

The main chamber and ice condenser chamber are designed according to the standards of ASME (Sec. VIII & BPE) and all GMP requirements are met in their construction.

#### ✓ **Refrigeration System**

The refrigeration system uses electronic expansion valve technology. All parameters of this subsystem are continuously measured and monitored. For this purpose, we use electronic temperature and pressure sensors in the refrigerant system and all temperature and pressure Parameters of the refrigeration cycle are shown in the software of the device and stored in the database.

#### ✓ **Vacuum System**

The control of vacuum pressure in our FD machines is performed by a needle valve and a high frequency solenoid valve to control the vacuum very fine. The vacuum pressure in the main chamber, condenser chamber and pump head is measured separately by Pirani gages.

#### ✓ **Heat Transfer System**

Heat transfer fluid is silicone oil 5cst and circulate with a stainless steel pump.

#### ✓ **Electrical &Control System**

Some of the important features of this subsystem are as follows:

- PC/PLC platform with Ethernet communication
- 10 freezing and 16 primary drying steps
- System status on every screen
- Synoptic overview
- Maintenance/troubleshooting screen
- Manual operation
- Automatic system test with history data storage
- Automatic defrost
- Automatic leak rate test
- Graphical display of runs
- Numeric data collection by run – excel importable
- Out of range product thermocouple correction
- Remote monitoring and control capability
- Batch report
- 21 CFR Part 11 compliance module

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## Pilot Freeze Dryer Machine PFD-S3 Model

General Specification of Machine (PFD-S3)	
Overall Dimensions of Machine	1.4W*1.3D*1.6H (m)
Useable Sublimation Area	1m <sup>2</sup>
Shelf Dimensions	300mm*550mm
Shelves Number	6+1
Distance Between Shelves	45 mm
Shelves Temperature	-45 °C ~ +80°C
Ice Condenser Capacity	20 kg
Ultimate Ice Condenser Temperature	- 75 °C
Ultimate Vacuum Range	Less Than 0.02mbar (2Pa)
Control of Machine	PLC-HMI
Electrical Power	3-Phase, 380V, 50HZ

### 2) Main Chamber

Row	Items	Specification
1	Material	SS 304 L
2	Type of Chamber	Cylindrical
3	Surface Finish	Less than 0.6µm (Mechanical Polish)
4	View Port in Front	∅150mm
5	Insulation	Elastomeric NBR

### 3) Ice Condenser

Row	Items	Specification
1	Material	SS 304 L
2	Type of Chamber	Cylindrical (Vertical)
3	Ice Capacity	20 kg total
4	Type of Condenser	Coil
5	Time for Ambient Temperature to -50°C	Less than 20 min
6	Isolation Valve between two chambers	DN150 Mushroom Valve (option)
8	Surface Finish	Less than 0.6µm (Mechanical Polish)
9	View Port in Side	1x ∅100mm
10	Insulation	Elastomeric NBR

### 4) Refrigeration System

Row	Items	Qty.	Specification
1	Compressor	1	Bitzer (Germany)
2	Refrigerant	1	R404A

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3	Heat Exchanger	1	Danfoss (Denmark)
4	Oil Separator	1	Castel (Italy)
5	Water Condenser	1	Sabcool (IRAN)
6	Thermostatic Expansion Valve	2	Danfoss /EMERSON-USA (option)
7	Refrigeration equipment	-	Danfoss (Denmark)-Castel (Italy)
9	Insolation	-	K flex (Italy-Iran)

### 5) Shelves& Heat Transfer System

Row	Items	Qty.	Specification
1	Flatness of Shelves	6+1	Less than 0.5mm/m
2	Roughness of Shelves	-	Less than 0.6μm
3	Uniformity in Shelves	-	$\pm 1^{\circ}\text{C}/\text{m}^2$
4	Freezing Rate in Shelves (+20°C to - 40°C)	-	Less than 60min
5	Heating Rate in Shelves (-40°C to + 20°C)	-	Less than 60min
6	Circulation Pump	1	EBARA (Italy)
7	Piping Material	-	SS 304
8	Silicone Oil	15 L	5cst (Brand Name)
9	Electrical Heater	1	JC Heat

### 6) Vacuum System

Row	Items	Qty.	Specification
1	Evacuation Time (atm to 0.1mbar)	-	Less than 30min
2	2 stage Rotary Vane Pump	1	Woosung (Korea)
3	Vacuum Valve on Pump	1	EP-Bellows Seal Valve
4	Vacuum Pressure Control	-	EP Valve
5	Vacuum Back Fill & Break	1	Solenoid Valve (Italy)

### 7) Electrical, Instrument &Control System

Row	Items	Qty.	Specification
1	PLC & Expansion Module	Set	S7-1200, SIEMENS (Germany)
2	HMI	1	SIEMENS (Option)
3	Electrical panel	1	FTM
4	Electrical Device (Interface Relay & Contactor)	-	LS, Finder
5	Controller Device (Thermostat & Data Logger)	-	Hanyoung & Shivaamvaj
6	Temperature Sensor (PT100)	4	JUMO
7	Vacuum Sensor	1	APG 100 (EDWARDS)
8	Hydraulic Device	Set	Duplomatic, BOSCH
9	Pneumatic Device	Set	PENUMAX/Shako

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### 8) Documentation

TAPCO, based on the quality management standard (ISO9001-2015) in the design and manufacturing of the Freeze drying machines, provides the technical and qualitative documentation of its own Freeze drying machines. This documentation includes the following:

- Certificate of final testing of the construction of subsystems
- Certificate of final testing of system assembly
- Installation Qualification Checklist
- Operation Qualification Checklist

In addition to the above qualitative records, the following are also delivered as technical documentation of the product:

- Lay Out Drawing of Machine
- P&ID (For all subsystems)
- Electrical Circuit Drawing
- User Manual Book
- Maintenance Manual Book
- Part List

### 9) Tests

Qualification tests will be carried out on the basis of the approved protocols both at the factory and on the customer site. All bugs raised by the customer representative in the factory acceptance tests will be corrected and then the machine will be allowed to ship to the customer site.

Admission tests will also be carried out on the customer site and the device will be delivered to the customer.

### 10) Packing& Shipping

The device and its accessories will be properly packaged and listed and sent to the customer by a truck. The cost of transport and insurance must be paid by the customer.

### 11) Installation & Training

The machine is installed and commissioning by the TAPCO experts on the customer site.

All trainings needed to work with Freeze dryer will be given to operators.

### 12) Guaranty& After Sales Services

The machine is fully guaranteed after delivery to the customer for one year. After completing the guaranty period, TAPCO providing after-sales service and spare parts for this machine.