

# PILOT - FREEZE DRYING SYSTEMS

Dual chamber system with separation valve and vacuum control - 5 to 40kg



Engineering under high pressure  
Made in Germany



**ZIRBUS**  
TECHNOLOGY

# ZIRBUS TECHNOLOGY GMBH

Since its founding in 1984, ZIRBUS technology GmbH, as a German manufacturer, has gained an outstanding reputation on the international market. We manufacture not only freeze dryers and autoclaves but also focus on process technology. A steadily increasing number of customers is putting their trust in Zirbus brand autoclaves and lyophilizers.



## Our customers' satisfaction is our top priority...



**TOGETHER WITH OUR CUSTOMERS, WE CONTINUALLY DEVELOP NEW SOLUTIONS FOR VARIOUS AREAS OF APPLICATION**



**WE TAKE ADVANTAGE OF EVERY POSSIBLE OPPORTUNITY FOR IMPROVEMENT**



**PERFECTION IN SERVICE IS WHAT DRIVES US**



**EFFICIENT AND RELIABLE TECHNOLOGY**



**A PERFECT COMBINATION OF SOFTWARE AND HARDWARE**



**TECHNICALLY PERFECTED AND VALIDATABLE PROCESS ENGINEERING**

## CERTIFIED QUALITY

**Modul H** certified

**EN ISO 9001** certified

The quality management (QM) system according to DIN EN ISO 9001 implemented and practiced at ZIRBUS technology GmbH provides the framework for our quality- and cost-oriented activities.

In addition, a risk management system is a component of the QM system.



MADE COMPLETELY OF STAINLESS STEEL



20- FREE DEFINABLE DRYING PROGRAMMES

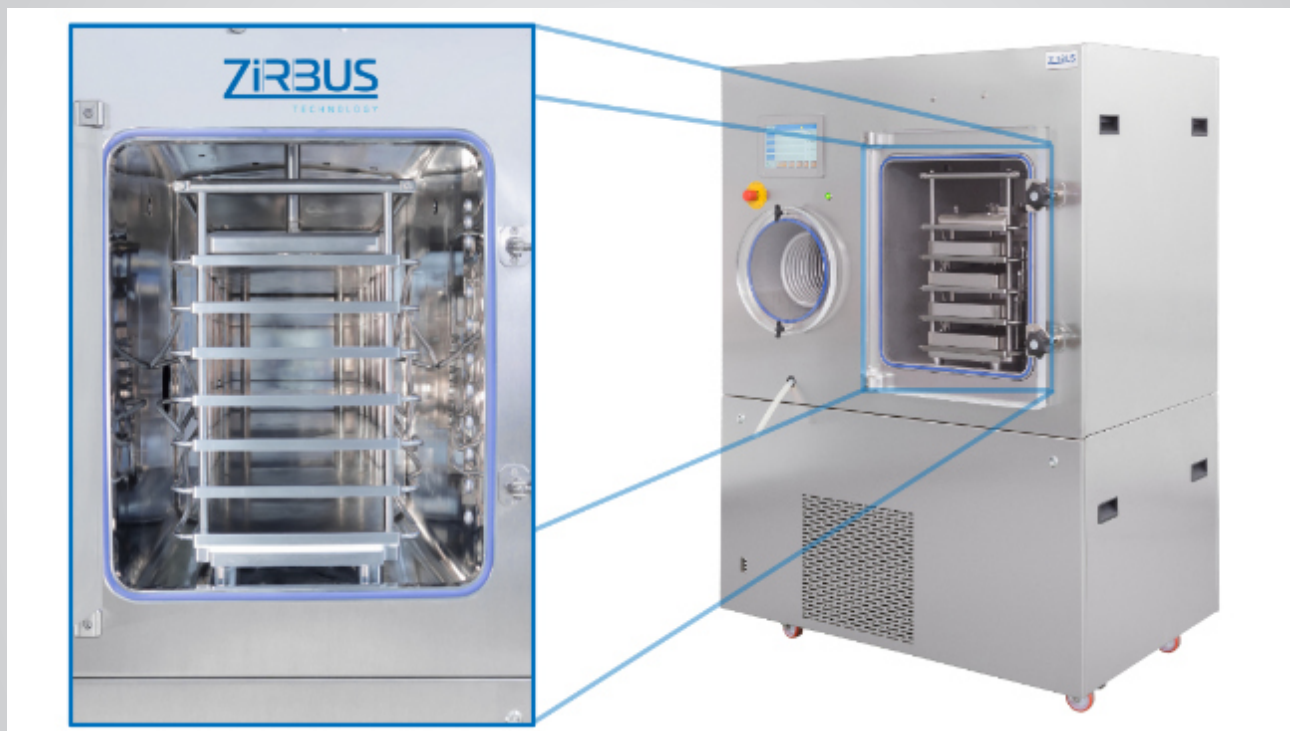


RECTANGULAR DRYING CHAMBER



ADDITIONAL CAPACITIVE VACUUM SENSOR (OPTIONAL)

Technical Data	Sublimator 5	
Drying chamber dimensions (W x H x D)	350 x 408 x 547 mm	
Condenser capacity	5kg / 24h, max. 6kg	
Condenser temperature	-50 oder -80°C	
Shelf temperature	-40...+60°C oder -60...+60°C	
System dimensions (W x H x D)	970 x 1700 x 750 mm	
Shelf type	Tray drying	Vial drying
Shelf size	200 x 450 mm	200 x 450 mm
Shelf configuration (Number + radiation panel) / Shelves / distance between shelves	2+1 / 0,18 m <sup>2</sup> / 130 mm	2+1 / 0,18 m <sup>2</sup> / 130 mm
	3+1 / 0,27 m <sup>2</sup> / 90 mm	3+1 / 0,27 m <sup>2</sup> / 90 mm
	4+1 / 0,36 m <sup>2</sup> / 58 mm	4+1 / 0,36 m <sup>2</sup> / 58 mm
	5+1 / 0,45 m <sup>2</sup> / 44 mm	



DUAL- CHAMBER SYSTEM WITH SEPARATION VALVE



USER - DEFINED FREEZE - DRYING PROCESSES



INTEGRATED VACUUM PUMP



WALL MOUNTING (GAS - TIGHT)

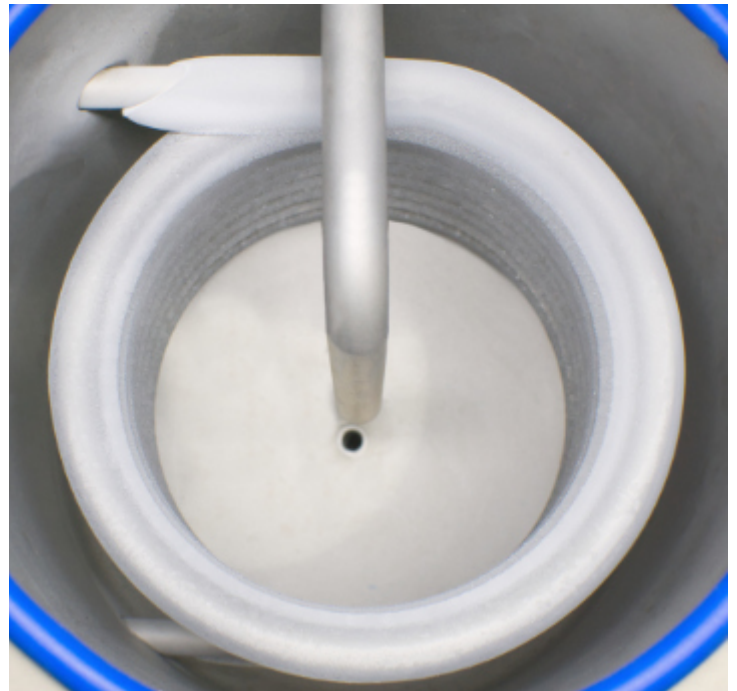
Technical Data	Sublimator 15	
Drying chamber dimensions (W x H x D)	400 x 600 x 650 mm	
Condenser capacity	10kg / 24h, max. 15kg	
Condenser temperature	-50 oder -75°C	
Shelf temperature	-40...+60°C oder -55...+60°C	
System dimensions (W x H x D)	1300 x 1850 x 850 mm	
Shelf type	Tray drying	Vial drying
Shelf size	320 x 500 mm	250 x 500 mm
Shelf configuration (Number + radiation panel) / Shelves / distance between shelves	5+1 / 0,80 m <sup>2</sup> / 75 mm	3+1 / 0,38m <sup>2</sup> / 130 mm
	6+1 / 0,96 m <sup>2</sup> / 60 mm	4+1 / 0,5m <sup>2</sup> / 95mm
	7+1 / 1,12 m <sup>2</sup> / 50 mm	5+1 / 0,63 m <sup>2</sup> / 75 mm
		6+1 / 0,75 m <sup>2</sup> / 60 mm

## Visible ice condenser

Condenser can be cleaned quickly and easily.

Icing status is easy to monitor.

Lid is also available in a chemical - resistant, stainless steel design with an integrated sight glass (optional).



## Variable shelf package with hydraulic closure

Our variable shelf package allows you to position shelves at ideal intervals for your job - without having to replace the shelf package.

Shelf intervals can be adjusted without tools.

This makes the system highly flexible.

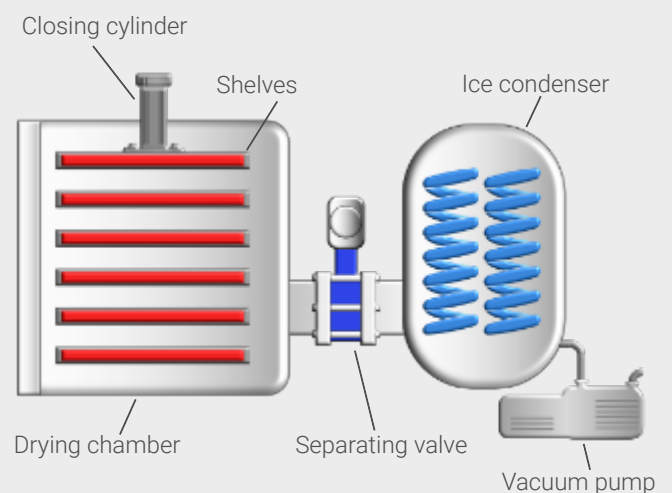
## Pressure rise measurement

This measurement allows you to determine the end point for the primary drying step.

To this end, the ice condenser is separated from the drying chamber by means of a valve.

The pressure increase is determined in the chamber within a defined period of time.

The result can be used for extrapolating the degree of dryness.



Ex. Sublimator 40



SHELVES WITH LIQUID TEMPERATURE CONTROL, UNIFORM ( $\pm 1^{\circ}\text{C}$ )



REPRODUCIBLE PROCESSES



STOPPERING SYSTEM FOR VIALS, HYDRAULIC



INDUSTRIAL PLC WITH TOUCH PANEL

Technical Data	Sublimator 25	
Drying chamber dimensions (W x H x D)	500 x 650 x 650 mm	
Condenser capacity	20kg / 24h, max. 25kg	
Condenser temperature	-50 oder -75°C	
Shelf temperature	-40...+60°C oder -55...+60°C	
System dimensions (W x H x D)	1500 x 1920 x 944 mm	
Shelf type	Tray drying	Vial drying
Shelf size	420 x 600 mm	350 x 600 mm
Shelf configuration (Number + radiation panel) / Shelves / distance between shelves	3+1 / 0,76 m <sup>2</sup> / 180 mm	3+1 / 0,63 m <sup>2</sup> / 160 mm
	4+1 / 1,01 m <sup>2</sup> / 130 mm	4+1 / 0,84 m <sup>2</sup> / 120mm
	5+1 / 1,26 m <sup>2</sup> / 100 mm	5+1 / 1,05 m <sup>2</sup> / 100 mm
	6+1 / 1,51 m <sup>2</sup> / 80 mm	6+1 / 1,26 m <sup>2</sup> / 80 mm
	7+1 / 1,76 m <sup>2</sup> / 65 mm	7+1 / 1,47 m <sup>2</sup> / 65 mm
	8+1 / 2,02 m <sup>2</sup> / 55 mm	

## Connection to a glovebox / isolator

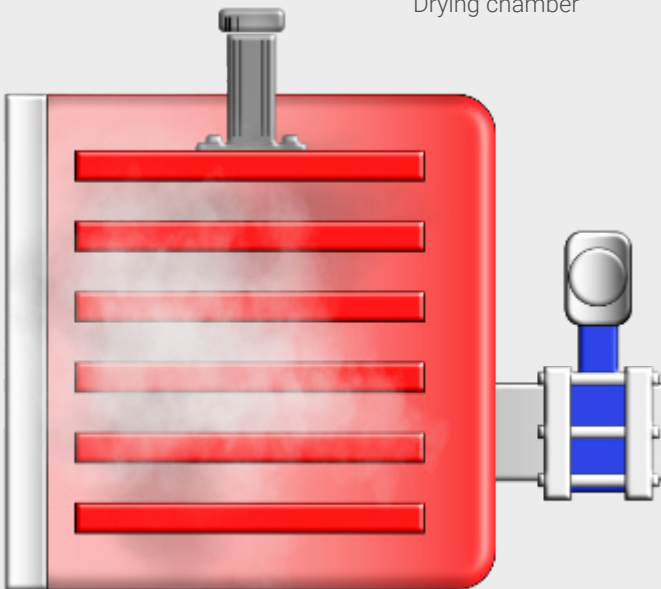
In certain applications, the user may need to be protected from the product or the product may need to be kept separate from the environment.

Our freeze dryers can be adapted and connected to a variety of isolators by means of a connecting flange.

For loading purposes, the freeze dryer chamber is separated from the surrounding atmosphere and from the user.



Drying chamber



## SIP: steam or H<sub>2</sub>O<sub>2</sub> sterilization

SIP (sterilization in place) describes the sterilization option that comes with the freeze dryer.

The chamber and condenser can be sterilized in preparation for lyophilization.

This can be done using H<sub>2</sub>O<sub>2</sub> or, if preferred, via steam sterilization at temperatures of up to 125 °C.

## CIP: cleaning in place

This describes the chamber and condenser cleaning function.

Spray nozzles arranged at geometrically optimum points clean the chamber and condenser of any residues.

Fluorescent substances indicate the success of the cleaning step.

Available only with GMP-compliant chambers.





**EXPLOSION - PROOF DESIGN, SOLVENT PURGE**



**VISUALIZATION SOFTWARE (AUDIT- TRAIL; CFR 21 PART 11)**



**WATER -COOLED REFRIGERATION SYSTEM**



**COMPACT CONSTRUCTION, ONLY 980 mm WIDE**

Technical Data	Sublimator 40	
Drying chamber dimensions (W x H x D)	700 x 700 x 850 mm	
Condenser capacity	30kg / 24h max. 40kg	
Condenser temperature	-50 oder -75°C	
Shelf temperature	-40...60°C oder -55...+60°C	
System dimensions (W x H x D)	980 x 1920 x 1650 mm	
Shelf type	Tray drying	Vial drying
Shelf size	450 x 750 mm	450 x 750 mm
Shelf configuration (Number + radiation panel) / Shelves / distance between shelves	5+1 / 1,69 m <sup>2</sup> / 100 mm	4+1 / 1,35 m <sup>2</sup> / 125 mm
	6+1 / 2,03 m <sup>2</sup> / 80 mm	5+1 / 1,69 m <sup>2</sup> / 100 mm
	7+1 / 2,36 m <sup>2</sup> / 67 mm	6+1 / 2,03 m <sup>2</sup> / 80 mm
	8+1 / 2,70 m <sup>2</sup> / 57 mm	7+1 / 2,36 m <sup>2</sup> / 67 mm



**Visualization and documentation incl. audit trail / CFR 21 part 11**



The visualization of processes is used to monitor and control production. In areas where the highest quality standards must be maintained, it is essential to visualize processes and document them in a secure manner. After all, the batch protocol is used as proof that all parameters have been met.

It therefore makes sense that this data cannot be changed later and that a record is kept of who, when and what has been changed.

Rights can be assigned individually via user administration and everything is recorded via the audit trail. The FDA defines an audit trail as a secure, computer-generated and time-stamped electronic record.

**Advantages of our visualization software**

- ✓ All user rights are assigned individually.
- ✓ Program modifications are documented with a time stamp and archived over the entire service life.
- ✓ Records and date cannot be modified after the fact.
- ✓ 2- Factor Identification (ID + password)
- ✓ Digital signature
- ✓ Audit trail: a secure, computer-generated, time-stamped electronic record.



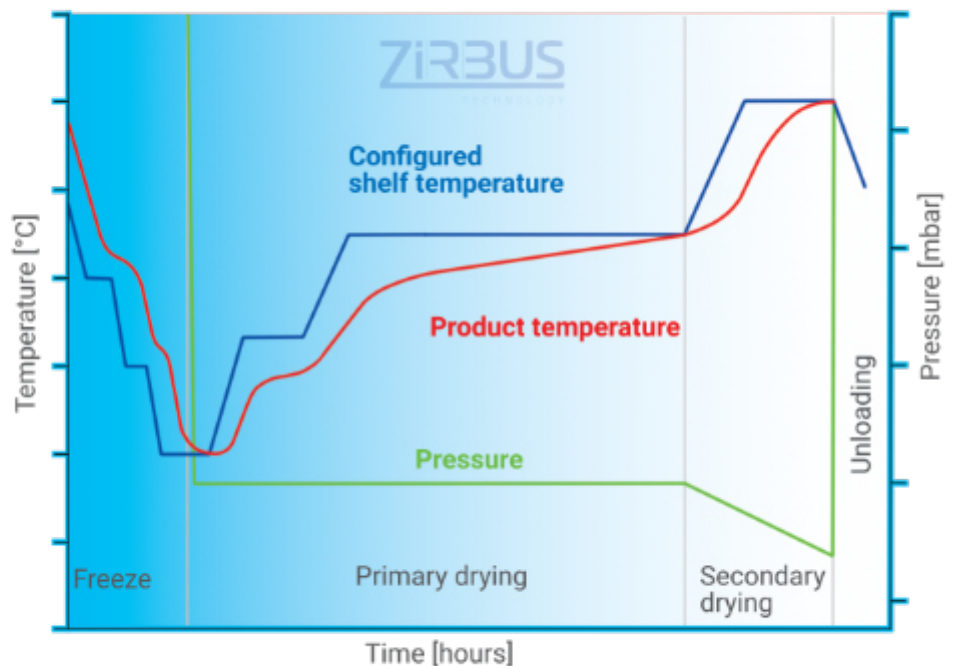
**Freeze drying process**

**1. Freezing:**

When freezing a product, users can customize temperature gradients and hold times. This influences the formation of ice crystals, which, in turn, can favor gas transport.

**2. Primary drying:**

The next step after freezing is to generate a vacuum, potentially defining individual temperature gradients and hold times. The goal here is to introduce energy in the form of heat as a means of accelerating sublimation. Users can precisely define the vacuum in order to obtain reproducible results. The more liquid sublimates, the closer the product temperature will come to the value set for the shelf.



**3. Secondary drying:**

During secondary drying, the physical conditions are adjusted once again, in this case for the purpose of removing absorbed water from the sample via sublimation. Here the vacuum is set to the highest possible level and the temperature is selected in such a way as to prevent damage to the product.

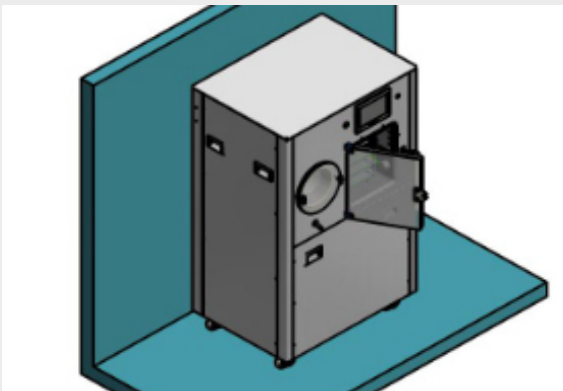


### Sublimator 40 with CIP , SIP

Applications: drying raw materials for the pharmaceutical industry

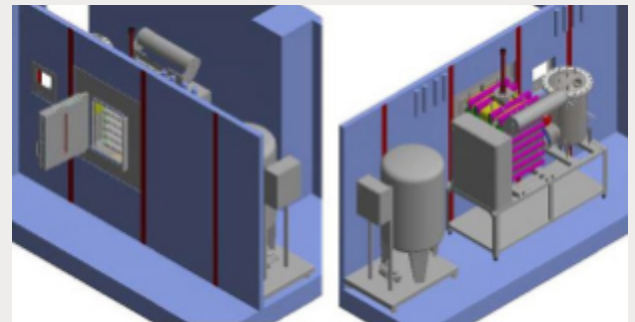
This sublimator has a total shelf area of 2.36 m<sup>2</sup> and comes equipped with 7+1 shelves.

The temperature of the ice condenser is -75 °C, with a capacity of up to 40 kg/24 h.



### Sublimator 5 (air-tight housing)

The unique task involved in this project was to keep explosive mixtures away from potential sources of ignition. For this reason, the housing was designed to be air-tight for operation in an ATEX environment.



### Sublimator 15

A classic lyophilizer for pharmaceutical production.

This model has an air-tight wall insert that separates the product chamber from the technical area.



### Sublimator 25 incl. glovebox / isolator

When conducting research on and with pathogens, care must be taken to ensure that these cannot leave the processing chamber and enter into the environment.

Protecting the product from external influencing factors may be valuable as well, however.

Our glovebox – specially tailored for the lyophilizer – does all of that.

One unique feature is that users can decouple it and then hook it up to an autoclave.

**SERVICE**

We offer you outstanding service. Our employees regularly take part in training sessions to make high-quality service possible.

**HOTLINE**

Our technical hotline will assist you regarding operation and if you are having system- or process-related problems. If you need us, we can get to you within 24 hours.

**REPLACEMENT PARTS**

.We process spare parts deliveries immediately. Delivery is generally made the same day

**CONSULTATION**

We can provide you with advice regarding your project and draw on our experience to assist you. Sample sterilizations can also be carried out in our application laboratory.

**OUR SERVICES INCLUDE:**

Delivery, installation and training	Maintenance and Service
Calibration with DKD (German Calibration Service)-tested measuring instruments	Validation according to recognized guidelines
Qualification DQ / IQ / FDS, SDS, HDS /OQ / PQ according to GMP guidelines	Customized process development and optimization
Sterilization and drying on a contract basis in our own application laboratory	





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