Pilot freeze dryers
coolvacuum.com

Coolvacuum
a Dara Pharma company

LyoLab Mini

LyoLab

LyoLab+

Recipe development
at the highest level
and non-aseptic
batch production.



DOMINIQUE DUTSCHER SAS

LyoLab Mini | LyoLab | LyoLab+

Accuracy and control | Condenser's capacity up to 40 kg | Output for 2R up to 9,000 vials

Coolvacuum's pilot freeze dryers are specially designed to develop and analyze small batches before scaling them up to production facilities.

Control and precision in freeze-drying have been the core objectives when developing our pilot range, which features the same Base Software as the production equipment, along with configuration settings for data acquisition systems.

The cycle control and the machine configuration to the specific needs and applications of our clients, make Coolvacuum's pilot range equipment an ideal tool for any laboratory or small production plant.



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LyoLab Mini

- 640 x 630 x 1,655 mm.
- Ice condenser temperature up to -85 °C.
- Ice condenser capacity up to 6 kg.
- Output for 2R up to 535 vials.



LyoLab

- 1,300 x 850 x 1,800 mm.
- Ice condenser temperature up to -85 °C.
- Ice condenser capacity up to 30 kg.
- Output for 2R up to 4,440 vials.



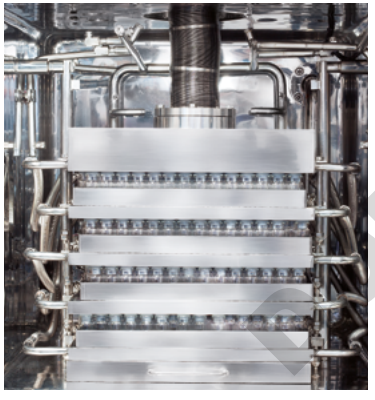
LyoLab+

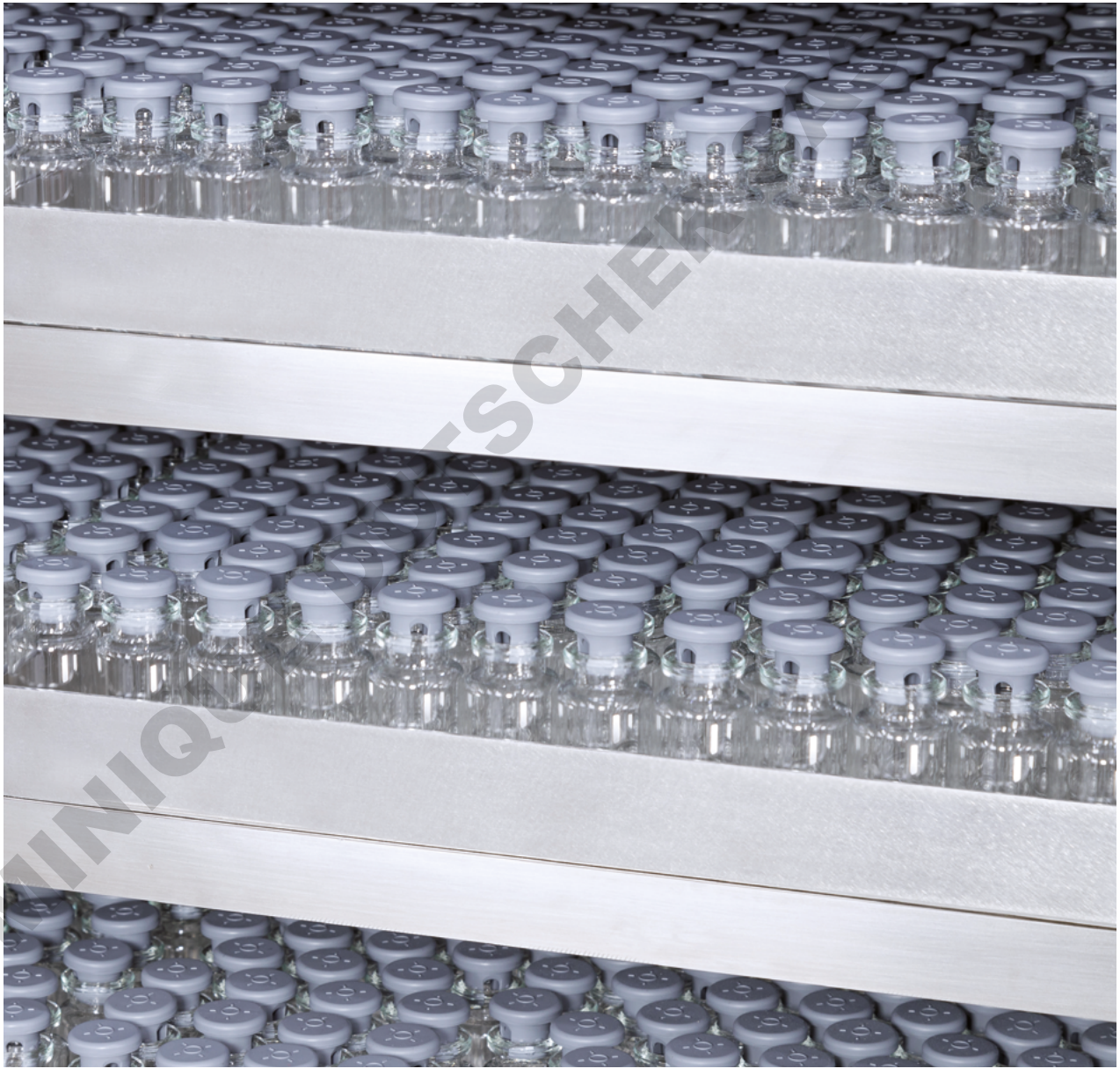
- 1,300 x 980 x 2,000 mm.
- Ice condenser temperature up to -85 °C.
- Ice condenser capacity up to 40 kg.
- Output for 2R up to 9,000 vials.

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UNIQUE FISCHER

Equipment's configuration

	LyoLab Mini		LyoLab		LyoLab+	
	0.06	0.12	0.5	1.0	1.5	2.0
Vials stoppering system						
Pneumatic vial stoppering	—		○	○	—	
Hydraulic vial stoppering	—		●	●	—	
Manual vial stoppering	●		—	—	—	
Cooling system						
Hermetic compressors in cascade	●		●		●	
Air-cooled	●		●	○	—	
Water-cooled	—		○	●	●	
Instruments						
Product temperature probes: PT100	1	2	3	6	9	12
Fluid temperature probe: PT100	●		●		●	
Fluid temperature probe (1 per shelf): PT100	1	○	○		○	
Condenser temperature probe: PT100	●		●		●	
Pirani vacuum sensor	●		●		●	
Capacitive vacuum sensor	○		○		○	
Airing system						
Airing of the chamber through cleanroom air	●		●		●	
Aligned HEPA filter	●		●		●	
Through N2 (1bar (a))	●		●		●	
Automatic vacuum control through controlled leak	●		●		●	
Cleaning system						
CIP (pipelines, sprinklers, and liquid ring pump)	—		○		○	
VHP disinfection (peroxide of hydrogen steam)	—		○		○	
Performance data						
Temperature range of shelves during drying process	from -50 °C to +70 °C		from -60 °C to +80 °C			
Shelves cooling speed	from 20 °C to -40 °C ≤ 60 min					
Shelves heating speed	≥ 1 °C/min					
Shelves uniformity	≤ ± 1 °C					
Condenser minimum temperature	-85 °C		≤ -85 °C			
Condenser cooling speed	from 20 °C to -40 °C ≤ 30 min					
Vacuum evacuation time	from 1,000 mbar to 0.1 mbar ≤ 30 min					
Final vacuum of freeze dryer	≤ 0.01 mbar (leak rate of 0.03 mbar l/s)					

Notes
● Standard
○ Optional
— Not available

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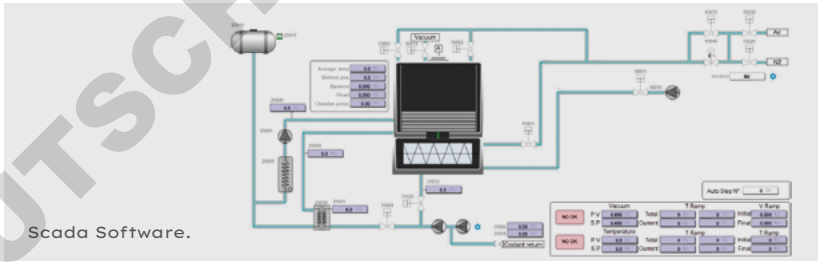
Software

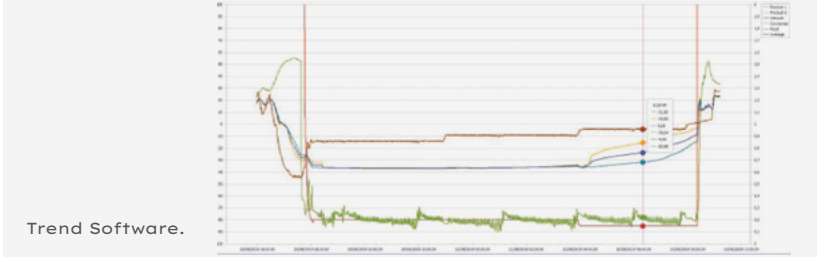
Coolvacuum leading automation solutions for freeze-drying processes offer a safe, reliable and user-friendly control and data acquisition for the system.

In R&D and drug development, data recording and recipe adjustment are of special importance, as they define, develop, and set the parameters for efficient future production and obtaining maximum performance from the freeze-dried product. All automation and controls are designed to current GAMP guidelines and comply with CFR21 part 11 regulations.



Base Software.


Scada Software.


Trend Software.

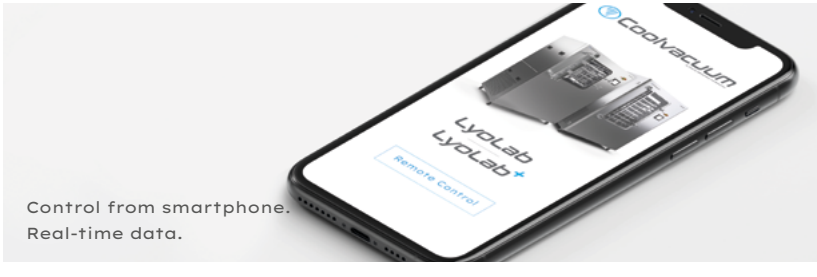
Remote Access

Regardless of the level of the software used, Coolvaccuum's pilot range freeze dryers can be remotely controlled from a mobile phone, through an intuitive app, making the production cycle monitoring more confortable.

In case a customer owns several freeze dryers, the app allows to access each one of them for a more efficient production organization.

In addition, the app allows to change the production parameters of the pilot range equipment, just as if it could be done from the touch screen of the Software Base level.

Furthermore, with a previous customer's authorization, Coolvacuums's technicians can get connected to a freeze dryer through a mobile phone for remote technical support.



Control from smartphone.
Real-time data.

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Base Software

Users	Register with different user levels from the freeze dryer's control screen.
Recipe programming	Enter the freeze-drying recipes parameters from the control screen.
Data export	Production data can be extracted via USB or memory card.

Scada Software

Users	Register with different user levels through a PC.
Recipe programming	Recipes can be programmed remotely from the control PC. All recipes or movements are recorded by Audit Trail.
Data export	All recorded data is reflected in the cycle report ensuring maximum reliability and reproducibility of the process. Some of the features: • Single file of the process with direct traceability (audit). • Alarms notification by email. • Data Integrity Compliant.

Trend + Base Software

Registered data can be transferred to a computer via Ethernet and later consulted by lot number or date.

The program generates graphs automatically.



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Coolvacuum's pilot freeze dryers have been designed with the same robustness as the production equipment to develop and define freeze-drying recipes at the highest level. Constructed in stainless steel, the freeze dryers can be paneled for their integration in cleanrooms.

Our LyoLab range freeze dryers with stainless steel chambers and condensers with the capacity of up to 9,000 vials and 40 kg of ice, can be equipped with a movable shelves system for vials stoppering, as well as other options on demand.

LyoLab Mini is also equipped with a condenser with the capacity of up to 540 vials and 9 kg of ice, and a movable shelves system for vials stoppering. Lyo-Epic, being a compact equipment, offers the same features as LyoLab and is designed for small batches freeze-drying during the recipe development stage.



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Reference / Model	LyoLab Mini		LyoLab		LyoLab+	
Shelves area	0,06 m²	0,12 m²	0,5 m²	1 m²	1,5 m²	2,0 m²
Shelves size	200 x 300 mm		380 x 450 mm			
Number of shelves	1 + 1	2 + 1	3 + 1	6 + 1	9 + 1	12 + 1
Shelves clearance	70 mm	120 mm	90 mm	65 mm	90 mm	65 mm
Product contact parts	AISI 316 L stainless steel					
Condenser capacity	12 kg		30 kg		40 kg	
Vacuum pump flow	12 m³/h		24 m³/h		30 m³/h	
Heating power	180 W		1,000 W		3,000 W	
Overall dimensions (W x D x H)	640 x 630 x 1,655 mm		1,300 x 850 x 1,800 mm		1,300 x 980 x 2,000 mm	
Weight	250 kg		700 kg	1,000 kg	1,400 kg	1,500 kg
Ice condenser capacity / 24h	5 kg		15 kg		20 kg	

PRODUCTION GMP

FREEZE DRYING EQUIPMENT

online ecatalogue

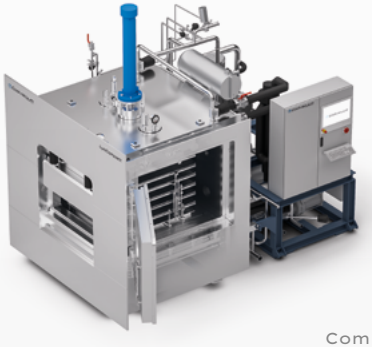


LyoNano

For small batches

From 0.5 to 2.5 m²

Designed for aseptic batches.
Compact and adaptable.

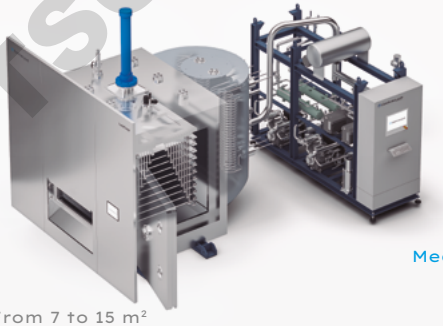


LyoCompact

Small scale production

From 2 to 6 m²

Compact solutions. Cutting-edge technology with a reduced footprint.



LyoCool

Medium scale production

From 7 to 15 m²

Optimal balance.
Maximum flexibility.

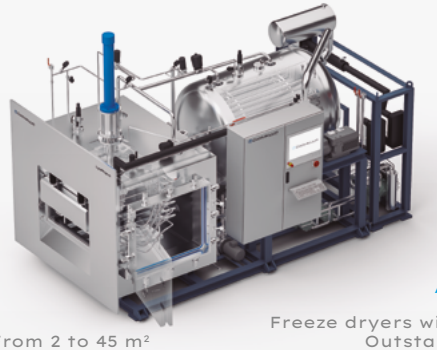


LyoPro

Large scale production

From 16 to 45 m²

Maximum performance.
Large-scale security and reliability.



LyoPharm

All types of production

From 2 to 45 m²

Freeze dryers within everyone's reach.
Outstanding standardization.

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Our commitment, your guarantee.

Coolvacuum is a synonym for trust and reliability. Our pursuit of excellence and customer-oriented service complements our high-quality equipment and high level of commitment. Coolvacuum offers, from the very beginning, a wide and flexible range of products and services designed to provide you with optimal support and ensure the machine's performance at its full capacity.

Coolvacuum's range of service 4.0, following the "Flexibility in motion" concept, takes advantage of cutting-edge technological advances, such as augmented reality or predictive maintenance, to provide the best technical support in terms of quality, efficiency, effectiveness, and response time.

Our technicians are available 24/7 to assist and solve any technical problems remotely worldwide. Coolvacuum's service excellence is achieved thanks to a cross-functional team of more than 15 nationalities and personalized customer attention managers. Represented in more than 80 countries with continuous support from local offices and sales representatives.



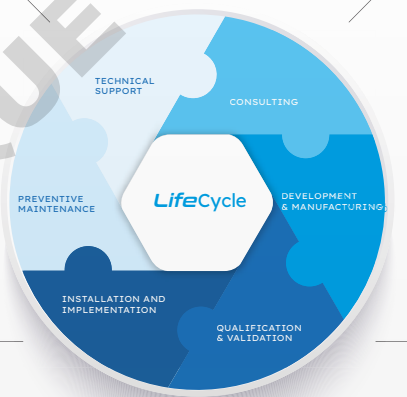
Worldwide assistance, present in more than 80 countries.

LifeCycle

Technical Support
Our team offers local and remote support to attend to attend any technical need.

Preventive Maintenance
We plan and adapt our interventions and specific actions to your production calendar.

Installation and Implementation
It is essential to adapt to the client's requirements, so that our interventions at the clients facilities have the least possible impact on their activity.



Consulting
Understand and satisfy customer's needs to find personalized solutions.

Development and Manufacturing
The services are planned and executed in a clear, direct, and rigorous way.

Qualification and Validation
All the necessary services are documented and executed so that the products are easily validated.

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Documentation and qualification

In pharmaceutical production, Good Manufacturing Practices (GMP) are essential to guarantee that the manufacturing process is constantly controlled according to the quality standards so the drugs can be used safely.

Therefore, there must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process, ensuring clarity and traceability of the product quality data acquisition. At Coolvacuum, we defined specific actions to ensure that our document management, which we call GDP (Good Documentation Practices), fulfills this objective.

The qualification documentation can be adapted to the specific needs of the client offering an individual approach.

DESIGN PROTOCOLS

- Qualification Project Plan (QPP).
- Functional and Design Specifications (FDS).
- Hardware Design Specifications (HDS).
- Software Design Specifications (SDS).
- Risk Assessment (RA).

TEST PROTOCOLS

- Design Qualification (DQ).
- Computer System Validation (CSV).
- Factory Acceptance Test (FAT).
- Site Acceptance Test (SAT).
- Installation and Commissioning (IAC).
- Installation Qualification (IQ).
- Operational Qualification (OQ).
- Record of qualification deviations.
- Record of qualification change controls.



DOMINIQUE DUTSCHER SAS

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Flexibility in motion

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