



coolvacuum.com

FREEZE DRYING EQUIPMENT

Production and laboratory
freeze dryers for the pharmaceutical
and nutritional industries



Coolvacuum

a Dara Pharma company



Focused on quality, innovation, and technological excellence

Since it was founded in Barcelona in 1996, **Dara Pharma** has followed a path towards quality, innovation, and technological excellence, developing and manufacturing stand-alone equipment and complete production lines for washing, sterilizing, filling, and closing of vials, bottles, syringes, cartridges, and IV Bags to process liquid, semi-solid products, and powders in sterile conditions.

In 2020, in order to offer more comprehensive solutions, Dara Pharma acquired **Coolvacuum**, a manufacturer of freeze dryers, and established the **Dara Pharma Group**.



Coolvacuum was founded in 2008 as a specialized company providing maintenance and upgrades to existing freeze-drying equipment all across Spain.

In 2012, Coolvacuum, having gained technological expertise, took another step forward and committed themselves to the manufacturing of their own freeze-drying equipment, offering tailor-made solutions in accordance with the quality standards of the pharmaceutical industry.

In 2020, Coolvacuum became part of the **Dara Pharma Group** and Dara has become a global manufacturer capable of offering turn-key solutions for freeze-dried injectable drugs.

Currently, the company addresses the needs of the pharmaceutical, chemical, nutritional, and cosmetic sectors, laboratories and R&D centers.

AFTER-SALES SERVICE

Supporting locally, acting globally

We have created a cross-functional team of more than 15 nationalities to give excellent after-sales service.

Our team is represented in more than 80 countries with continuous support from local offices and sales representatives.



📞 EUROPE +34 93 737 67 15 · USA +1 (872) 204 1449

✉️ service@dara-pharma.com



CONTENTS

04

Laboratory equipment

LYOMICRON | LYOEPIIC | TRIEPIC

06

Pilot equipment

LYOLAB MINI | LYOLAB | LYOLAB+

08

GMP production equipment

LYONANO | LYOCOMPACT | LYOCOOOL | LYOPRO | LYOPHARM

21 Loading systems

22 INTEGRA™ Control architecture and software

24 Protection and containment systems

25 Turn-key solutions

26

Bulk formats production

LYOBIOTIC

28

Plate freezers

BIOFREEZER MINI | BIOFREEZER | BIOFREEZER+

29

Documentation and qualification

30

LyoTech Center and After Market

Excellence and safety for the demanding standards of the pharmaceutical and biotech industry

Coolvacuum, **UNE-EN-ISO9001** certified, maintains a rigorous quality management system that integrates continual improvement processes to achieve the highest quality and safety standards, aimed mainly at the pharmaceutical sector. Our equipment is designed in compliance with **FDA**, **GMP** and **GAMP5**, and can be operated in the pharmaceutical industry worldwide.





Laboratory equipment

Laboratory freeze dryers

Reliability and flexibility for all your applications

Our laboratory freeze dryers are specially designed to meet the freeze-drying requirements of the most demanding industrial R&D departments as well as laboratories and universities.

Coolvacuum offers a wide range of accessories, adaptable to the requirements of our customers, to achieve the optimal freeze-drying process for each application.



LyoMicron



420 x 630 x 380 mm



Ice condenser capacity up to 7 kg



LyoEpic



540 x 630 x 970 mm



Ice condenser capacity up to 18 kg

TriEpic

TriEpic has been created for shared use of multiple formats and infinite freeze drying, when the equipment is required at different times and for different cycles.



1,840 x 630 x 970 mm



Ice condenser capacity up to 30 kg



Coolvacuum's Infinity Technology™ allows maintaining infinite freeze-drying cycles, alternating two condensers automatically when they reach their maximum capacity. While one condenser is in use, the other one can be drained to avoid downtime.

Model	LyoMicron		LyoEpic		TriEpic	
Ice condenser temperature	-55 °C	-85 °C	-55 °C	-85 °C	-55 °C	-85 °C
Overall dimensions (W x D x H)	420 x 630 x 380 mm	740 x 600 x 380 mm	540 x 630 x 970 mm		1,840 x 630 x 970 mm	
Ice condenser capacity	7 kg		18 kg		30 kg	
Electrically heated shelves			Optional			
Vacuum pump flow	6 m ³ /h		12 m ³ /h		36 m ³ /h	
Weight	65 kg	85 kg	95 kg	120 kg	140 kg	150 kg
Ice condenser capacity / 24h	5 kg		8 kg		16 kg	



Laboratory
equipment

Wide range of accessories



Accessories	Shelves		Neoprene valves		Shelf area m ²		Clearance (mm)	Height increase (mm)	
	Dimensions (mm)	Quantity							
Manifolds	-	-	6	12	-	-	-	310	560
Circular chamber for Micron	Ø 200	6	8	-	0.18	0.24	40	440	
with vials stoppering		3 + 1	-	-	0.09	-	70	510	
with electrical heating		6	8	-	0.18	0.24	35	440	
with electrical heating and stoppering		3 + 1	-	-	0.09	-	65	510	
top cover with manifold		6	8	6	0.18	0.24	40	440	
Circular chamber for Epic	Ø 370	6	-	-	0.66	-	60	650	
with vials stoppering		4 + 1	6 + 1	-	0.43	0.66	78	725	990
with electrical heating		6	-	-	0.66	-	55	650	
with electrical heating and stoppering		4 + 1	6 + 1	-	0.43	0.66	75	725	990
top cover with manifold		6	-	8	0.66	-	60	650	
Rectangular acrylic chamber for Micron with / without electrical heating (W x D)	320 x 390	5	-	-	0.62	-	43	450	
Rectangular acrylic chamber for Epic with / without electrical heating (W x D)	425x 390	5	-	-	0.82	-	43	480	

Optional configurations

- Condenser -55 °C / -85 °C.
- Hot gas defrosting system.
- SCADA software for data recording, alarm management and audit trail, based in the INTEGRA™ control platform (see page 22).
- Remote connection.
- Vacuum control for cycle optimization.
- Chamber / condenser isolation valve.
- Organic solvent condenser.
- Gas discharge filter for the vacuum pump.
- Infinite condenser for continuous freeze drying.



Pilot equipment

Pilot freeze dryers

Ready for scale up

Coolvacuum pilot freeze dryers are designed for customers that want to develop and optimize freeze drying recipes and be able to scale up to a production unit.

Our range of pilot freeze dryers, featuring five sizes and a wide portfolio of optional equipment and software configurations, will give you the capability to manufacture small batches, and perform detailed analysis of your production challenges.



**LyoLab
MINI**



640 x 626 x 1,655 mm



Ice condenser capacity up to 6 kg



LyoLab



1,250 x 850 x 1,970 mm



Ice condenser capacity up to 30 kg



LyoLab+



1,250 x 1,400 x 1,990 mm

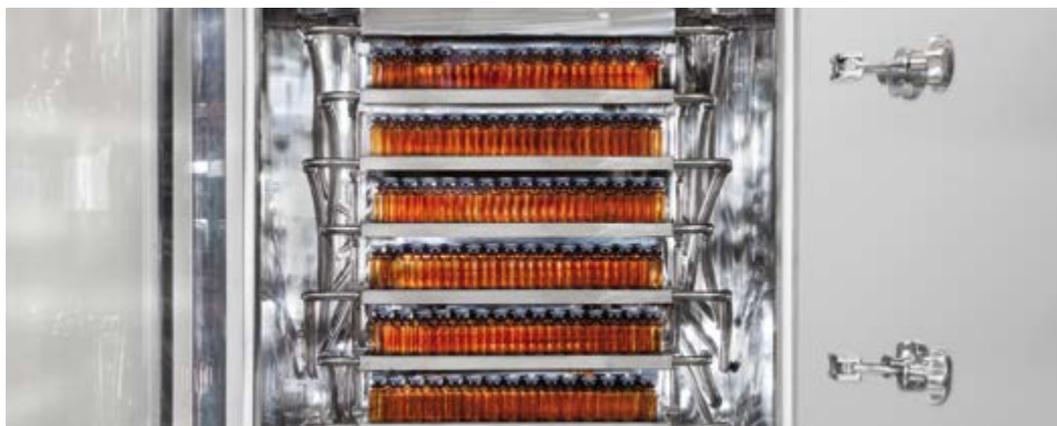


Ice condenser capacity up to 40 kg



Pilot equipment

Accuracy and control, fully tailor-made



Vial batch ready for freeze drying.

Model	LyoLab MINI	LyoLab		LyoLab ⁺	
Shelf area	0.06 m ² / 0.12 m ²	0.5 m ²	1 m ²	1.5 m ²	2 m ²
Shelf dimensions (W x D)	200 x 300 mm	380 x 450 mm			
N° of shelves	1 + 1 / 2 + 1	3 + 1	6 + 1	9 + 1	12 + 1
Shelves clearance	120 mm / 70 mm	90 mm	65 mm	90 mm	65 mm
Product contact parts	Stainless steel AISI 316L				
Condenser capacity	6 kg	30 kg		40 kg	
Vacuum pump flow	12 m ³ /h	30 m ³ /h		36 m ³ /h	
Condenser temperature	-85 °C				
Shelves temperature range	from -50 °C to +70 °C	from -60 °C to +80 °C			
Heating power	500 W	1,000 W		3,000 W	
Overall dimensions (W x D x H)	640 x 626 x 1,655 mm	1,250 x 850 x 1,970 mm		1,250 x 1,400 x 1,990 mm	
Weight	300 kg	1,200 kg	1,400 kg	1,600 kg	1,800 kg
Ice condenser capacity / 24h	5 kg	15 kg		20 kg	

Optional configurations

- Chamber / condenser isolation valve.
- Vials stoppering.
- Manifold for bottles.
- Paneled front for clean rooms integration.
- Eutectic point control.
- Nucleation control.
- SCADA software for data recording, alarm management and audit trail, based in the INTEGRA™ control platform (see page 22).
- CIP and sanitization by VHP.
- Chamber configurations with two heights between shelves.
- Organic solvent condenser.
- Wireless temperature probes.
- Vial sampling device.
- Capacitive pressure sensor.
- Comparative pressure reading.
- Ethernet connectivity (remote connection).



GMP production equipment

Production freeze dryers

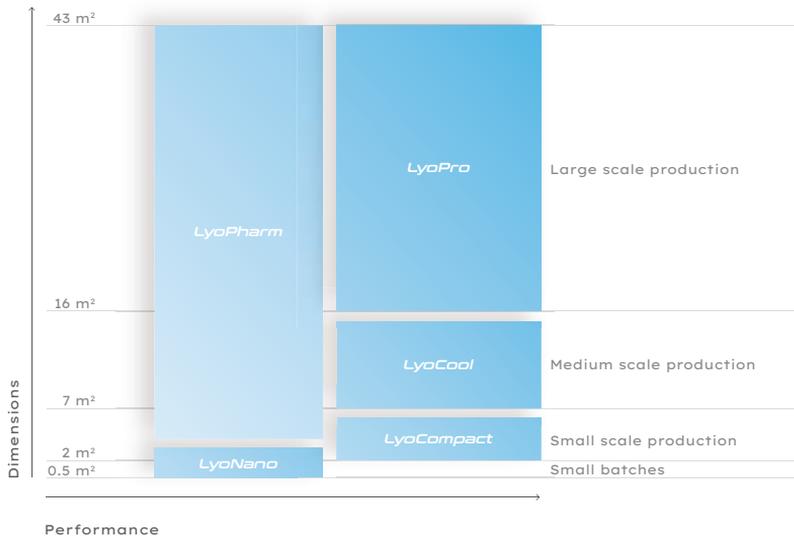
Customized compact and effective solutions

Coolvacuum has developed a complete range of industrial freeze dryers, with a useful shelf area from 0.5 to 43 m², to cover different production needs.

With five basic models and more than 40 optional features, Coolvacuum freeze dryers can be adapted

to the specific needs of our clients.

Using only the best and most reliable materials and components, our equipment complies with the quality levels expected by the pharmaceutical industry.



Vial loading capacity

Shelves m ²	1	1,5	2	3	4	5	6	8	10	12	14
Ø 16 mm (2R-4R)	4,440	6,660	8,880	13,320	17,760	22,200	26,640	35,520	44,400	53,280	62,160
Ø 22 mm (6R-8R)	2,340	3,510	4,680	7,020	9,360	11,700	14,040	18,720	23,400	28,080	32,760
Ø 24 mm (10R-15R)	1,970	2,955	3,940	5,910	7,880	9,850	11,820	15,760	19,700	23,640	27,580
Ø 30 mm (20R-25R)	1,250	1,875	2,500	3,750	5,000	6,250	7,500	10,000	12,500	15,000	17,500
Shelves m ²	15	18	20	22	24	26	28	30	32	38	45
Ø 16 mm (2R-4R)	65,000	79,920	88,800	97,680	106,560	115,440	124,320	133,200	142,080	168,720	200,000
Ø 22 mm (6R-8R)	35,100	42,120	46,800	51,480	56,160	60,840	65,520	70,200	74,880	88,920	105,300
Ø 24 mm (10R-15R)	29,550	35,460	39,400	43,340	47,280	51,220	55,160	59,100	63,040	74,860	88,650
Ø 30 mm (20R-25R)	18,750	22,500	25,000	27,500	30,000	32,500	35,000	37,500	40,000	47,500	56,250



GMP production equipment

Wide range of freeze dryers



LyoNano

- From 0.5 to 3 m²
- Up to 60 kg of ice
- Up to 13,000 2R vials



LyoCompact

- From 2 to 6 m²
- Up to 100 kg of ice
- Up to 26,600 2R vials



LyoCool

- From 7 to 15 m²
- Up to 260 kg of ice
- Up to 65,000 2R vials



LyoPro

- From 16 to 43 m²
- Up to 800 kg of ice
- Up to 200,000 2R vials



LyoPharm

- From 4 to 43 m²
- Up to 800 kg of ice
- Up to 200,000 2R vials

Quality and performance standards

Performance data

Sublimation rate	from 1 to 35 kg/h
Preparation time between batches (CIP / SIP, drying, cooling)	8 h

Chamber

Surface roughness	0.5 µm
System leak rate	0.008 mbar x l/s

Shelves

Flatness on shelf surface	1 mm/m
Surface roughness on top side (Ra)	0.5 µm
Surface roughness on bottom side (Ra)	0.5 - 1.4 µm

Temperature distribution on one shelf	<1 °C
---------------------------------------	-------

Temperature distribution in shelves stack	<1.5 °C
---	---------

Temperature difference between the inlet and outlet of a shelf	<1 °C
--	-------

Condenser

Surface roughness	0.8 µm
Surface roughness of condenser coil	Cold drawn
Defrosting time	from 20 to 60 min

Evaporation surface ratio vs shelf surface	0.99 m ² /m ²
--	-------------------------------------

Cooling and heating

Shelves cooling rate from +20 °C to -40 °C	1.5 °C/min
--	------------

Shelves heating rate from -40 °C a +60 °C	1.5 °C/min
---	------------

Temperature range during drying	from -50 °C to +60 °C
---------------------------------	-----------------------

Condenser cooling rate +20 to -40°C	1.5 °C/min
-------------------------------------	------------

Final condenser temperature	-75 °C
-----------------------------	--------

Vacuum

Final system vacuum	0.005 mbar
---------------------	------------

Final vacuum of freeze dryer	0.01 mbar
------------------------------	-----------

Vacuum evacuation time from 1,000 a 0.1 mbar	30 min
--	--------



GMP production equipment
Small batches

LyoNano

Designed for aseptic batches

Compact construction complying with GMP

CIP / SIP equipment

Wide range of optional equipment

Panels for clean rooms



From 0.5 to 3 m²
of shelf area



Condenser capacity
up to 60 kg



Output for 2R up to
13,000 vials





GMP production equipment
Small batches

Compact and adaptable

During pharmaceutical and biotechnological development, high value-added and personalized products undergo highly demanding, small-batch processing, with full regulatory compliance obviously required.

Coolvacuum's LyoNano model is the best choice for customers developing products in these circumstances. The LyoNano is equipped with technology available in our commercial units but for smaller batch sizes, and it is in full compliance with commercial regulation and procedure.



Vial batch ready for freeze drying.

Model	LyoNano							
Shelf area	0.5 m ²	1 m ²	1.4 m ²	1.7 m ²	2.1 m ²	2.4 m ²	2.7 m ²	3.1 m ²
Shelf dimensions (W x D)	380 x 450 mm			450 x 760 mm				
N° of shelves	3 + 1	6 + 1	4 + 1	5 + 1	6 + 1	7 + 1	8 + 1	9 + 1
Shelves clearance	90 mm	75 mm	105 mm	90 mm	75 mm	105 mm	90 mm	75 mm
Chamber material	Stainless steel AISI 316L							
Condenser capacity	30 kg		40 kg			60 kg		
Condenser temperature	-85 °C							
Shelves temperature range	from -60 °C to +85 °C							
Overall dimensions (W x D x H)	1,300 x 1,900 x 1,850 mm		2,000 x 2,500 x 2,500 mm			2,000 x 2,500 x 2,900 mm		
Weight	2,000 kg		3,000 kg			3,500 kg		



Optional equipment on page 20



GMP production equipment
Small scale production

LyoCompact

Compact solutions

Single body chamber and condenser
Bottom shelf as intermediate valve

Reduced plant footprint

Standalone frame for cooling system

Standalone frame for vacuum system



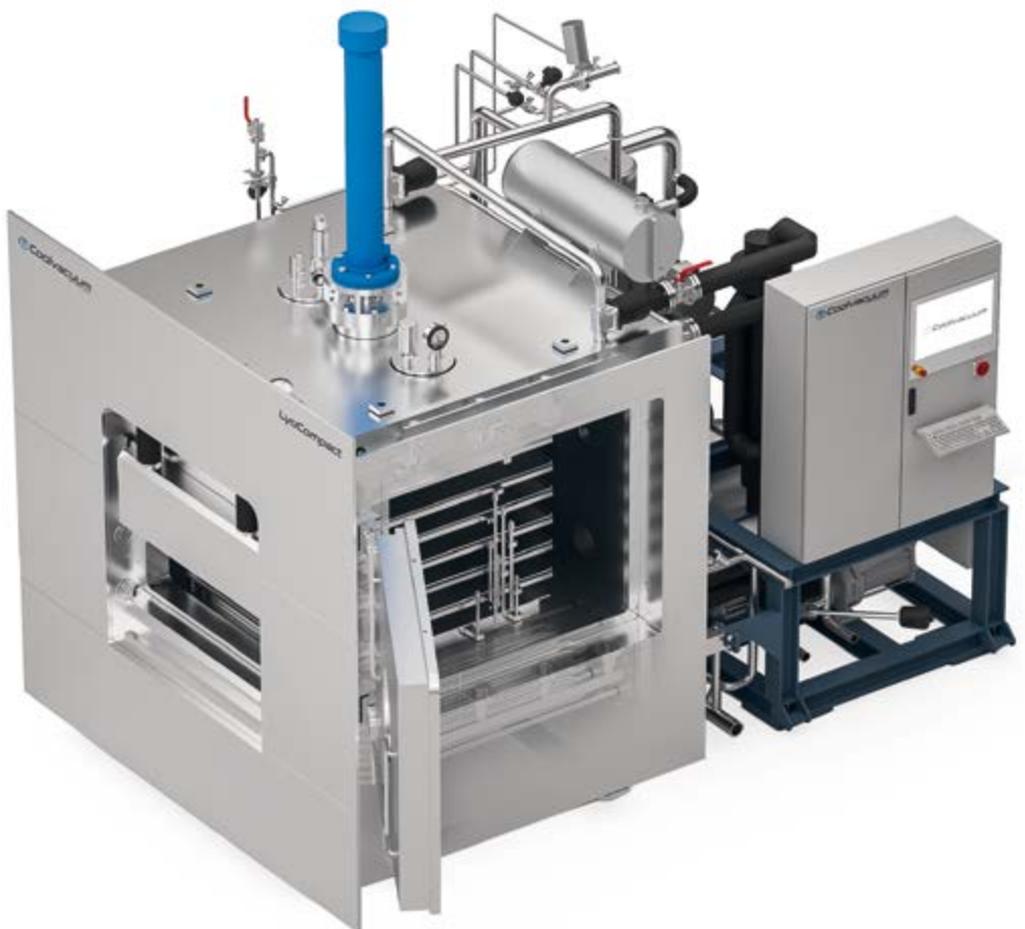
From 2 to 6 m²
of shelf area



Condenser capacity
up to 100 kg



Output for 2R
up to 26,600 vials





GMP production equipment
Small scale production

Cutting-edge technology with a reduced footprint



When production needs require the latest technology, operating under the highest market standards, **Coolvacuum** LyoCompact is a groundbreaking solution. This range of freeze dryers combines a compact design and the highest quality components, features versatile software, and is manufactured using the latest in engineering design.

LyoCompact easily adapts to any space, thanks to its modular design. The vials can be loaded manually or automatically. In addition, the LyoCompact model includes an integrated condenser and uses the bottom shelf as an intermediate valve.

Integrated condenser.

Model	LyoCompact					
Shelf area	2.16 m ²	2.88 m ²	3.6 m ²	4.32 m ²	5.04 m ²	5.76 m ²
Shelf dimensions (W x D)	800 x 900 mm					
N° of shelves	3 + 1	4 + 1	5 + 1	6 + 1	7 + 1	8 + 1
Shelves clearance	105 mm	90 mm	75 mm	105 mm	90 mm	75 mm
Chamber width	1,750 mm					
Chamber height	3,100 mm			3,500 mm		
Condenser capacity	65 kg			100 kg		
Condenser temperature	-85 °C					
Shelves temperature range	from -60 °C to +85 °C					



Optional equipment on page 20



GMP production equipment
Medium scale production

LyoCool

Optimal balance

Single body chamber and condenser
Mushroom valve as intermediate valve

Compact and modular design

Standalone frame for cooling system

Standalone frame for vacuum system



From 7 to 15 m²
of shelf area



Condenser capacity
up to 260 kg



Output for 2R
up to 65,000 vials





GMP production equipment
Medium scale production

Maximum flexibility to face new market challenges

An increase in production volumes needs to be accompanied by commensurate manufacturing equipment sizing. Here, **Coolvacuum** offers the LyoCool range. LyoCool provides a perfect balance between compact design and a cooling system capable of managing large production batches.



Modular design.

LyoCool is distinguished by its flexibility and can operate with any type of product, regardless of its freeze-drying characteristics. The LyoCool freeze dryer is designed to fit into existing production plants and can be configured for optimal production design.

Model	LyoCool					
Shelf area	7.2 m ²	8.64 m ²	10.08 m ²	11.52 m ²	12.96 m ²	14.4 m ²
Shelf dimensions (W x D)	1,200 x 1,200 mm					
N° of shelves	5 + 1	6 + 1	7 + 1	8 + 1	9 + 1	10 + 1
Shelves clearance	105 mm	90 mm	75 mm	105 mm	90 mm	75 mm
Chamber width	2,200 mm					
Chamber height	3,800 mm			4,200 mm		
Condenser capacity	180 kg			260 kg		
Condenser temperature	-85 °C					
Shelves temperature range	from -60 °C to +85 °C					



Optional equipment on page 20



GMP production equipment
Large scale production

LyoPro

Maximum performance

External condenser in 1 or 2 floor configuration

Mushroom or butterfly valve as intermediate valve

Continuous circular coil in condenser

Standalone frame for cooling system

Standalone frame for vacuum system



From 16 to 43 m²
of shelf area



Condenser capacity
up to 800 kg



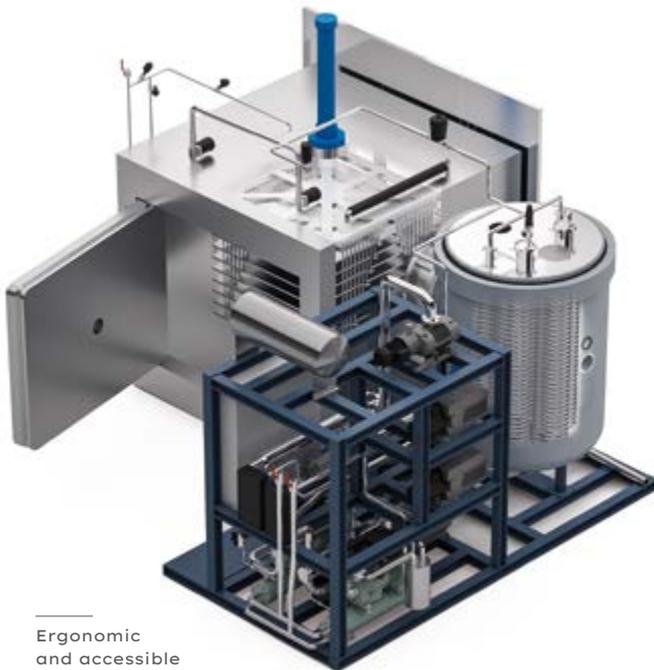
Output for 2R
up to 200,000 vials





GMP production equipment
Large scale production

Large-scale security and reliability



Ergonomic and accessible design.

Do you need a high-performance freeze dryer for large scale production?

Coolvacuum offers a solution for this requirement, our LyoPro model. This freeze dryer enables safe, large-scale freeze drying, has been designed for easy installation, and has maximum flexibility. As the flagship of the Coolvacuum family of freeze-dryers, the LyoPro range has been designed to feature precise control, in order to manage large batch freeze drying with the same efficiency and exactness as that of small batches.

With cooling and vacuum systems that are compact in size, and built from the highest quality materials, this model is unrivaled in quality and capability.

Model	LyoPro												
Shelf area (m ²)	16.8	19.2	21.6	24	26.4	28.8	31.2	33.6	36	38.4	40.8	43.2	
Shelf dimensions (W x D)	1,500 x 1,600 mm												
N° of shelves	7 + 1	8 + 1	9 + 1	10 + 1	11 + 1	12 + 1	13 + 1	14 + 1	15 + 1	16 + 1	17 + 1	18 + 1	
Shelves clearance (mm)	105	90	75	105	90	75	105	90	75	105	90	75	
Chamber width	2,600 mm												
Chamber height	3,800 mm			4,200 mm			4,600 mm			5,000 mm			
Condenser capacity	400 kg			525 kg			650 kg			800 kg			
Condenser temperature	-85 °C												
Shelves temperature range	from -60 °C to +85 °C												



Optional equipment on page 20



GMP production equipment

LyoPharm

Freeze dryers within everyone's reach

Standardized configuration of chamber, condenser, cooling and vacuum systems

External condenser connected by butterfly valve

Side or front maintenance door



From 4 to 43 m² of shelf area



Condenser capacity up to 800 kg



Output for 2R up to 200,000 vials



Model	LyoPharm								
Shelf area (m ²)	4.32	5.04	5.76	7.2	8.64	10.08	11.52	12.96	14.4
Shelf dimensions (W x D)	800 x 900 mm			1,200 x 1,200 mm					
N° of shelves	6 + 1	7 + 1	8 + 1	5 + 1	6 + 1	7 + 1	8 + 1	9 + 1	10 + 1
Shelves clearance (mm)	105	90	75	105	90	75	105	90	75
Chamber width	1,750 mm			2,200 mm					
Chamber height	3,500 mm			3,800 mm			4,200 mm		
Condenser capacity	100 kg			180 kg			260 kg		
Tray dimensions	300 x 400 mm								
Condenser temperature	-85 °C								
Shelves temperature range	from -60 °C to +85 °C								



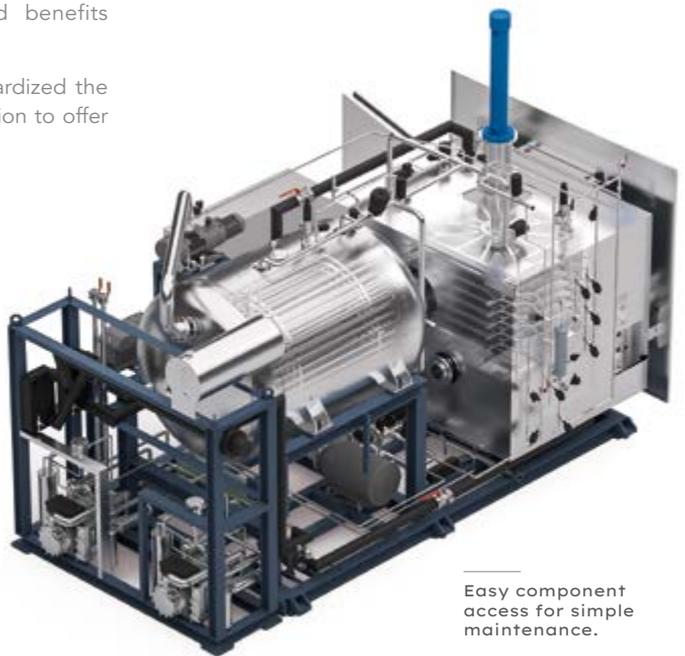
GMP production equipment

Outstanding standardization

LyoPharm is an excellent example of the balance between the investment made and benefits obtained.

Coolvacuum has designed and standardized the best configuration for each vial dimension to offer high-performance equipment at affordable prices.

Additionally, the standardization of its components and configurations allows us to manufacture LyoPharm with reduced delivery times.



Easy component access for simple maintenance.

LyoPharm											
16.8	19.2	21.6	24	26.4	28.8	31.2	33.6	36	38.4	40.8	43.2
1,500 x 1,600 mm											
7 + 1	8 + 1	9 + 1	10 + 1	11 + 1	12 + 1	13 + 1	14 + 1	15 + 1	16 + 1	17 + 1	18 + 1
105	90	75	105	90	75	105	90	75	105	90	75
2,600 mm											
3,800 mm			4,200 mm			4,600 mm			5,000 mm		
400 kg			525 kg			650 kg			800 kg		
300 x 400 mm											
-85 °C											
from -60 °C to +85 °C											



Optional equipment on page 20



Production equipment
Production freeze dryers

Optional equipment

LyoNano | LyoCompact | LyoCool | LyoPro | LyoPharm

The chamber

- Rectangular chamber
- Pressureless vessel
- Injected foam insulation
- Cooling by cold water circuit

Connection with condenser

- Butterfly valve
- Mushroom valve
- Bottom shelf closing

Ice condenser

- Integrated underneath, on the same floor
- Integrated on the side, on the same floor
- Outside, behind the camera, on the same floor
- Outside, under the camera, on another floor

Shelf movement

- Closing system hydraulic piston
- Bellows
- Connection with automatic charging system

CIP

- Chamber and condenser cleaning system
- Recirculation system with heating
- Multiple cleaning cycles

SIP

- PED-EN13445
- ASME
- Chamber cool-down after SIP

Plant distribution

- 1st floor
- 2 floors
- Passthrough system

Additional elements

- ATEX (processed with solvents and alcohol)
- Cold tray loading
- Frozen tray loading
- Nucleation technology

Refrigeration

- Piston compressor
- Screw compressor
- Liquid nitrogen system
- Cascade system
- Cooling system without PCA
- Compressed air system

Door

- Full size door
- Automatic locking
- Slot front door (constant loading level)
- Full size sub-door
- Cooling by cold water circuit

Process sensors

- Pirani
- Capacitive
- Temperature probes (Pt-100 / Thermocouple)
- Redundant temperature probes (Pt-100 / Thermocouple)
- Wireless temperature monitoring
- Full batch traceability software

Control systems

- Rockwell / Siemens Automation PLC
- Integrated HMI
- SCADA
- Electronic recorder
- Electronic Server and Think Client
- Cycle optimization technology

Filter vent system

- Sterilizable
- Ports for integrity testing
- Secondary venting cycle
- Secondary vent filter
- Water filter integrity test

Vacuum system

- Sealed vacuum pumps with blowing system
- Redundancy (additional pump)
- Dry pumps with blowing system



Shelves stack.



Loading systems

Dara Pharma loading systems

The Dara Pharma Group is an expert in vial, syringes, and cartridges handling

Automation requirements, aimed at efficiency and reducing potential cross contamination in the loading / unloading area of freeze dryers, have evolved to the point that most new facilities already feature systems designed for integration to the filling line as well as the freeze-drying equipment.

The **Dara Pharma Group** provides solutions of this type, starting with the overall design, and continuing to the integration of the complete filling and freeze-drying lines at the Dara plant.

The Dara Pharma Group offers a wide range of full systems that can operate according to the needs of each client and selected application.

Manual loading and unloading

This type of system, mainly used in small facilities, allows the customer to manually load vials or bulk product either in trays or frames.

Semiautomatic loading and unloading

Dara Pharma has developed systems that combine manual operation for processes that are difficult to automate with other systems that are fully automated, to increase their efficiency.

Automatic loading and unloading

Dara's technical team will evaluate your automation requirements and specify the best transport system from among our many possible solutions.

Transfer carts

Carts can be fixed to both the filling line and the freeze dryer, for loading and unloading operation, using different technologies.

Buffer accumulation systems

Buffer accumulation systems allows coordination between the continuous motion filling system and the intermittent loading of the freeze dryer, yielding high efficiencies with an integrated system.

Model	NLS Nest loading system	VLS Vial loading system	VLS+ Vial loading system
Load sequence	PUSH-IN	PUSH-IN	PULL-IN
Unload sequence	PULL-OUT	PUSH-OUT	PUSH-OUT
Based technology	Robot	Servo cylinder	Servo chain
Output max.	115 Nest/h	12,000 uph	24,000 uph



Robotic system for the loading vials in Nest.



Row by row loading system (designed by Motus).



Control architecture and software

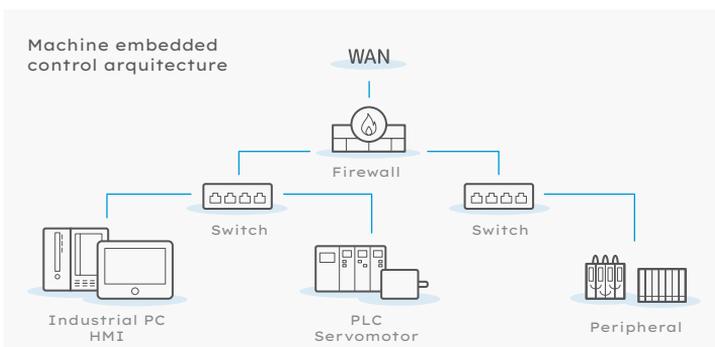
Reliable and easy batch control

Coolvacuum's automation concept is part of the control architecture designed by the **Dara Pharma Group**. It combines the automated freeze drying solutions, achieving a full integration in the aseptic closing line.

This way, the system is both secure and convenient, both for visualization and introduction of process data, with a single software solution for the complete line. In this product range, data capture and recipe adjustment become especially important; with them we can define, refine, and determine the parameters for efficient future production.

In that sense, **INTEGRA™** operates as a SCADA platform that provides maximum security to process and manage information consistently. These are some of its main features:

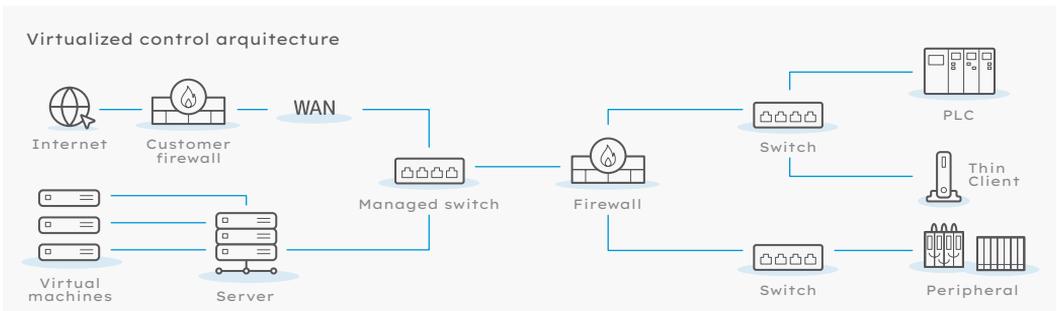
Individualized user management	Using different authorization levels, it is possible to create user groups according to function. It includes the "Administrator" role, with specific capabilities and a customized control panel. It connects directly to Windows active directory. It offers different authorization levels in each active element.
Recording	All the processes, operations, recipes, user events and alarms can be recorded, with the possibility of setting up their selection.
Alarm systems	Smart alarm management, with a customizable list and miscellaneous filters. It complies with the ISA 18.2 and IEC 62682 alarm administration standards.
Recipe programming	Recipe management with protected access for their creation, modification and implementation. Everything can be organized in groups (per machine, role, etc.) and by variable states according to the group, with easy to use filters for their selection, as well as import and export capabilities.
Reports	Administration of electronic SOP/POE operations with automatic workflows and batch report generation. Customizable according to GAMP5 SW cat. 4. À la carte Reporting (ready-to-use templates, universal data archive at all levels, real time and historical reports).



INTEGRA™ is focused on the CIM (Computer Integrated Manufacturing) pyramid for OT/IT convergence. Delivering HMI embedded SCADA or Virtualized solutions, we also provide customized services for the protocol conversion gateways used for data collection as well as a dashboard used for Enterprise integration (MES/ERP).



Full access to key information about their installation



INTEGRA™ is a SCADA solution, developed over the Zenon platform by Copa-Data, that offers a great range of ready to use features, as well as great versatility, while complying with FDA (21CFR part 11), GMP and GAMP regulations.

Functionalities	SCADA HMI EMBEDDED	SCADA EXTERNAL PC
SCADA	✓	✓
Basic reports of last batch	✓	✓
Historical report of batches in PDF	✓	✓
Weighing reports	Optional	✓
Calibration reports	Optional	✓
Exportation of reports to server	Optional	✓
Basic OEE report	Optional	✓
Advanced OEE report	✗	Optional
Customized report	Optional	Optional
Preemptive maintenance management	Optional	Optional
eSignature	Optional	✓
Integration of variables in client system	Optional	Optional
Integration of MES and SAP	Optional	Optional
Dara & Coolvacuum support	Optional	✓
Software visualization	Optional	Optional



INTEGRA™ Central Platform.



Supervision, control and data acquisition.



Protection and
containment system

Dara Pharma protection and containment equipment

Specific solution for any need

Due to growing concern for product and operator protection and the complex regulatory framework of the pharmaceutical industry, it has become essential to design the processing equipment together with the containment system.

Aseptic pharmaceutical manufacturing requires the production area to be free from microbiological and particle contamination. The environmental conditions for sterile processing are designed to maintain product sterility and are ISO 5 or Grade A classified, considering the following parameters:

- Particle level ($> 0.5 \mu\text{m}$) less than 3,520 particles/ m^3 .
- Vertical air flow laminarity.
- Humidity control.
- Temperature control.
- Air recirculation.
- Cleaning and decontamination procedures.

In accordance with these standards, **Dara Pharma** has developed a wide range of products for different environmental conditions and levels of protection:



LAF - Laminar Air Flow

A dynamic barrier of HEPA-filtered unidirectional air flow to move particles away from the filling / closing area.

The line must operate in a clean room grade B or higher.



ORABS - Open Restricted Access Barrier System

A physical barrier between the operator and the product in addition to the dynamic barrier of HEPA-filtered airflow (LAF), composed of a glass cabinet, gloves, transfer ports, etc.

The air is taken from and expelled directly into the room where the equipment operates.

The line must operate in a clean room grade B or higher.



CRABS - Closed Restricted Access Barrier System

A physical and hermetic barrier between the operator and the product. The air is recirculated through dedicated return air ductwork in a sealed chamber.

The system allows working at pressure differentials (upper / lower) to the surrounding environment, and monitors and controls the processing parameters (V, P, T, Hr, etc.).

The line must operate in a clean room grade B or higher.



ISOLATOR / MODULINE™

The highest available level of containment for both sterile and toxic products, equipped with a hermetic chamber, rapid transfer ports (RTP) and predefined action protocols. The system features a dedicated decontamination system (VHP), sterility control, particle sampling and operating parameters that allow operation in an ISO 8 or class D classified room.



Complete production lines

Turn-key Solutions

Dara Pharma has created the most complete and advanced range of multiformat equipment in the market, by evolving from manufacturing stand-alone machines to integrating complete

lines that can process formats in-nest or in bulk. Our systems also offer mixed solutions where customers can combine both options depending on the processing format.

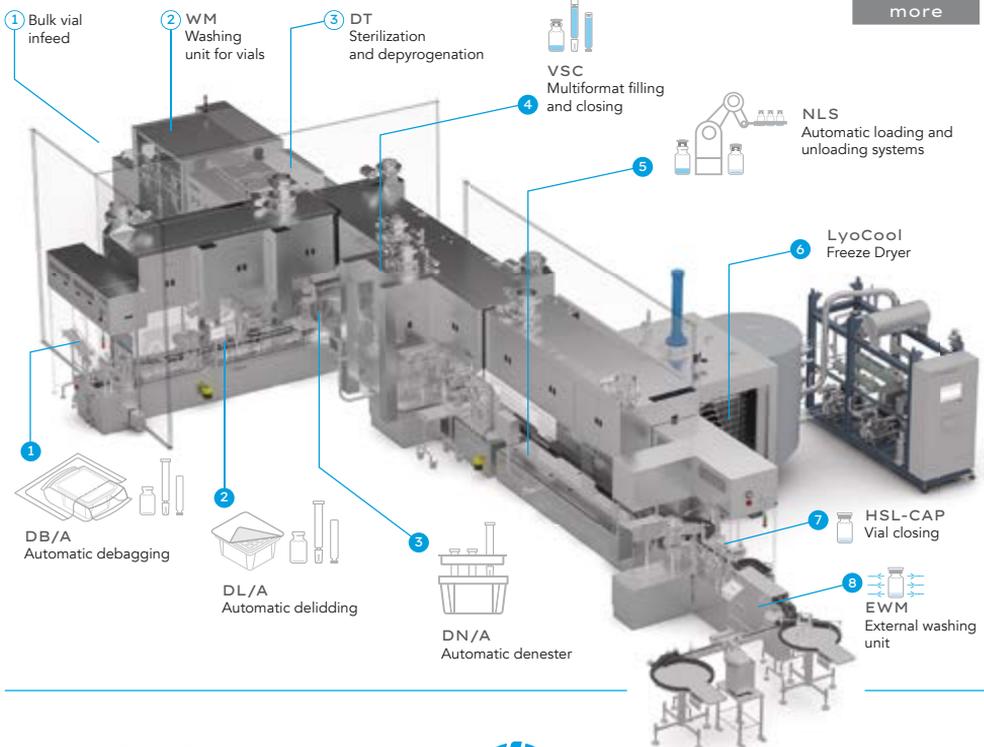
Multiformat line for aseptic packaging



UP TO 400 UPM



Learn more



Mechanical integration between machines

Design, manufacture, and adjustment of the transfer systems for the correct integration of all the machines of the line.



Architecture and single control: INTEGRA™

A control system configured for the entire line, so that all the machines operate under the same software and data acquisition system.



Complete service and maintenance

A complete maintenance plan for the entire line ensures that all machines will operate optimally and efficiently in the long term.



Bulk production
equipment

LyoBiotic

Freeze dryers for the probiotic and nutritional industries

Modular and compact design

Multiple configurations and options available

Being experts in freeze drying for the probiotic and nutritional industries, **Coolvacuum** has designed and developed the LyoBiotic line to offer superior quality equipment ready to be integrated into production lines.



From 5 to 100 m²
of shelf area



Condenser capacity
up to 1,500 kg



Model	LyoBiotic 5		LyoBiotic 10		LyoBiotic 20	
Overall dimensions (W x D x H)	1,500 x 1,950 x 2,150 mm		1,500 x 2,500 x 2,150 mm		2,900 x 3,700 x 2,500 mm	
Modules	1		1		2	
Condenser capacity	50 kg		90 kg		200 kg	
Shelf area	5.25 m ²		9.8 m ²		19.5 m ²	
Shelf dimensions (W x D)	700 x 1,500 mm		700 x 2,000 mm		1,050 x 1,550 mm	
N° of shelves	5 + 1		7 + 1		12 + 1	
Shelves clearance			50 mm			
Condenser temperature	-75 °C	-50 °C	-75 °C	-50 °C	-75 °C	-50 °C
Shelves temperature range	from -50 °C to +75 °C		from -50 °C to +75 °C		from -50 °C to +75 °C	
Weight	1,500 kg		2,500 kg		4,000 kg	



Bulk production equipment

Designed for bulk freeze drying

This equipment is a single chamber monoblock integrating the shelves and the condenser. Depending on the customer's requirements, redundant rotary vane pumps and / or Roots pumps are available to improve performance. Depending on the type of product to be freeze dried, single or double stage cooling systems can be included.

Our LyoBiotic line features a wide range of equipment for nutritional and probiotic freeze drying, with the following characteristics:

- Lower production cost
- Better equipment price
- Easily operated
- High-capacity and fast cycles
- Reduced footprint
- Latest technology

Freeze-dried products retain texture, nutritional value and complete flavor and are, therefore, widely used in the following fields:

- Nutritional supplements
- Probiotics
- Cosmetics
- Bone tissue and skin
- Marine plankton
- Food



LyoBiotic 30		LyoBiotic 50		LyoBiotic 100	
2,900 x 4,500 x 2,500 mm		4,250 x 5,800 x 3,300 mm		4,250 x 7,600 x 3,300 mm	
2		2		2	
400 kg		600 kg		1,200 kg	
29.3 m ²		50.4 m ²		100 m ²	
1,050 x 2,150 mm		1,200 x 2,100 mm		1,500 x 3,500 mm	1,000 x 3,500 mm
13 + 1		20 + 1		16 + 5	
50 mm					
-75 °C	-50 °C	-75 °C	-50 °C	-75 °C	-50 °C
from -50 °C to +75 °C		from -50 °C to +75 °C		from -50 °C to +75 °C	
6,500 kg		9,000 kg		15,000 kg	



Plate
freezers

Plate freeze-thaw systems

For biotech products and blood plasma

To obtain uniform and reproducible product freezing, we have created a range of plate freezers that cover both laboratory and production needs.

Only with powerful and efficient cold / heat groups, and through a precise heat transmission system through silicone fluid in plates, have we obtained

the desired uniformity and control for:

- Validation studies, process development and sampling.
- Storage in cell culture and subsequent purification processes.
- Storage and transport.



**BioFreezer
MINI**



640 x 630 x 1,655 mm



Up to 3 L (3 bags x 1 L)



BioFreezer



1,300 x 850 x 2,000 mm



Up to 40 L (8 bags x 5 L)



BioFreezer+



1,300 x 980 x 2,000 mm



Up to 40 L (2 bags x 20 L)

Model	BioFreezer MINI	BioFreezer	BioFreezer+
Shelf area	0.18 m ²	1.38 m ²	1.17 m ²
Shelf dimensions (W x D)	200 x 300 mm	380 x 450 mm	650 X 900 mm
Freezing capacity	3 L	40 L	40 L
Shelf position	Horizontal	Horizontal	Vertical
N° of shelves	3 + 1	8 + 1	2 + 1
Shelves clearance	45 mm	45 mm	200 mm
Bag range	from 5 ml to 1 L	from 5 ml to 5 L	from 1 L to 20 L
Shelves temperature range	from +70 °C to -70 °C	from +60 °C to -70 °C	
Overall dimensions (W x D x H)	640 x 630 x 1,655 mm	1,300 x 850 x 2,000 mm	1,300 x 980 x 2,000 mm



Documentation
and qualification

Documentation and qualification

Qualification and documentation offer customized for each client

In pharmaceutical production, Good Manufacturing Practices (GMP) are essential to guarantee that the manufacturing process is constantly controlled according to quality standards, and 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 have defined specific actions to ensure that our document management, which we call GDP (Good Documentation Practices), fulfills this objective.

The document management starts with the client's specifications (URS) which help us understand the customer's needs and define the equipment's configuration accordingly. The equipment's functionality will be tested later during the qualification tests.

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 Analysis (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

Coolvacuum's experts will take care of preparing and executing all necessary protocols.



Documentation package for GMP equipment.



Quality control.



LyoTech
Center

LyoTech Center

Learn and develop together

Coolvacuum's **LyoTech Center** is part of the **Dara Tech Center**, located at the **Dara Pharma** headquarters in Barcelona.

Since it was founded in 1996, Dara Pharma has followed a path of quality, innovation, and technological excellence. This is a path that could not have been followed without the investment in the latest technologies, together with the development of our own prototypes and systems, allowing us to offer the range of solutions for which Dara is well known today.

Coolvacuum offers complete services, such as:

- Training courses
- Recipe development
- Qualification of recipes
- Validation of recipes
- Product characterization
 - Thermal behavior
 - Eutectic temperature
 - Fusion temperature
 - Vitreous transition temperature
 - Collapse temperature
 - Freezing processes (Nucleation)
 - Primary / secondary drying phases
 - Humidity measure by high frequency
 - Humidity measure by Karl Fisher test
- Product quality improvement
 - Turbidity
 - Collapse
 - Pill shrinkage
 - Strata
 - Sedimentation
 - Concentration
 - Colored areas
 - Hardened top coat
 - Meltback
 - Boiling
 - Puffing
- Freeze-drying cycle time reduction
- Cycle adjustment to avoid vial breakage



Product study.



Freeze dried vials.



After Market

After Market

Always connected, always available

Coolvacuum is a synonym for trust and reliability. Our pursuit of excellence and customer-oriented service complements our high-quality equipment and our 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 to ensure optimal machine performance.

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.

Our support team is represented in more than 80 countries with continuous support from local offices and sales representatives.

TECHNICAL SUPPORT



Proactive services

Advanced training

Certification

Maintenance

Inspections

Reactive services

Dara Customer Service portal access

Remote technical support 24/7

Mechatronic staff availability in 24/48h

Augmented reality

Predictive maintenance – IoT

Life Cycle services

Spare parts

Customized spare parts

New formats

Retrofits

Upgrades



Worldwide assistance, present in more than 80 countries.



Express technical assistance in 24/48h.



FREEZE DRYERS

- LABORATORY
- PILOT
- GMP PRODUCTION
- BULK PRODUCTION

PLATE FREEZERS

LYO RECIPE DEVELOPMENT

Pol. Ind. Coll de la Manyà
Galileo Galilei, 13 · 08403 Granollers
Barcelona · SPAIN
t: +34 938 718 784

 
coolvacuum.com

Flexibility in motion