INDUSTRIAL-SCALE FREEZE DRYERS BUILT TO CUSTOMER SPECIFICATIONS.

Meet your specific manufacturing requirements with a bespoke lyophilizer from GEA.





FREEZE DRYING

GEA provides standard or customized solutions based on proven technology and a thorough understanding of the individual requirements for specific applications.



Application support.

Plant configuration extends from specialized solutions for highly potent products and layout requirements, and from two story units up to fully integrated systems with multiple freeze dryers and loading systems.

Our extensive experience in interface design guarantees the smooth integration of a perfectly harmonized production line. Based on your containment requirements and product details, we can help you to determine whether your specific application requires an ALUS® with open or closed RABS (Restricted Access Barrier Systems) or isolators.

Offering a variety of both standard and highly customized options, as well as the cost-effective SMART LYO® range, GEA's modular equipment extends from R&D to standalone production plants and high-capacity systems for bulk product applications.

Sustainability

GEA has developed an innovative air cycle solution for freeze dryers that uses natural refrigerants. The ATEXcompatible LYOAIR® system offers high levels of throughput and reliability with less vibration and quieter functionality. In addition, a carbon dioxide booster reduces energy consumption and eliminates the need to use explosive or toxic gases.

Production

LYOVAC[®] customized industrial freeze dryers designed in accordance with the latest cGMP regulationns. Ranging from 5-60 m² up to 1000 kg ice condenser capacity. The layout can be arranged on one or multiple floors in the building. Industrial freeze dryers (shelf size 5–60 m2) for large-scale production plants are also available and can be built to customer specifications. Small scale production including high potent materials. Variosys FCM 75i and FCM 150i.

LYOSPARK[®] Nucleation Technology

LYOSPARK[®] controlled nucleation technology from GEA facilitates uniform ice crystal formation in laboratory and production-scale freeze dryers with a minimum degree of supercooling. This is reflected in more consistent and larger ice crystal sizes with a more open product structure. As a result, faster drying and reconstitution times can be achieved. In addition, LYOSPARK[®] ensures inter-batch homogeneity, improves process repeatability and enhances both the presentation and quality of the final product.



LYOVAC® FCM 600-D.



Technical Data – Standard LYOVAC® Models

	Units	FCM 200	FCM 400	FCM 600	FCM 800
Chamber					
Geometry	Form	Rectangular	Rectangular	Rectangular	Rectangular
Shelves					
Shelf area	m²	10	20.4	30.2	41.22
No. of shelves	Quantity	9 + 1	<u>11 + 1</u>	13 + 1	15+1
Shelf size	mm	914 × 1219	1219 × 1524	1524 × 1524	1524 × 1803
Clearance	mm	125	125	125	125
No. of vials (Ø 16mm)	Batch size	42,759	87,527	129,662	177,000
No. of vials (Ø 22mm)	Batch size	22,464	46,057	68,302	93,240
No. of vials (Ø 30mm)	Batch size	11,970	24,607	36,530	49,875
Shelf temperature	°C	-55 +70	-55 +70	-55 +70	-55 +70
Condenser					
Geometry	Form	Cylindrical	Cylindrical	Cylindrical	Cylindrical
	Position	Laterally / behind	Laterally / behind	Laterally / behind	Laterally / behind
	Туре	Tube	Tube	Tube	Tube
Nominal ice capacity	kg	200	400	600	800
Chamber \ Condenser Valve					
Туре		Mushroom	Mushroom	Mushroom	Mushroom
Clear diameter	mm	500	700	900	1000
Weights					
Chamber and condenser (empty)	t	12.5	15	17.5	20

Technical Data – Utility Consumption

	Units	FCM 200	FCM 400	FCM 600	FCM 800	
Utilities						
Pure steam	barg	1,5	1,5	1,5	1,5	
	°C	127	127	127	127	
Consumption for sterilization*	kg	240	385	460	560	
Consumption for defrosting	kg	80	110	240	320	
CIP water	barg	3-4	3-4	3-4	3-4	
Temperature	°C	80	80	80	80	
Consumption*	m³	2,6	3,4	4,2	5	
Cooling water (Compressor)	°C	< 25	< 25	< 25	< 25	
Peak flow	m³/h	9	12	15	19	
Consumption	m³	138	175	212	267	
Electrical power supply	kW	105	140	175	210	
Power Consumption per Cycle*						
With compressors	KWh	650	900	1250	1700	
With liquid nitrogen	KWh	140	185	270	305	
LN₂ consumption	kg	1610	2040	3460	4030	

* Standard cycle

Technical Data – Base Values

	Units	FCM 200	FCM 400	FCM 600	FCM 800
Chamber					
Surface finish	μm	0,8	0,8	0,8	0,8
System leak rate	mbar x I /s	0,008	0,008	0,008	0,008
Shelves					
Flatness in the usable area	mm / m	1	1	1	1
Surface finish on top side Ra	μm	0,8	0,8	0,8	0,8
Surface finish on bottom side Ra	μm	1,6 - 2,2	1,6 - 2,2	1,6 - 2,2	1,6 - 2,2
Temperature distribution on one shelf	K	< 1	< 1	< 1	<1
Temperature distribution shelf stack	K	< 1,5	< 1,5	< 1,5	< 1,5
Difference between in- and outlet	K	< 1	< 1	< 1	< 1
Condenser					
Inner surface of the condenser	Finish	Pearl blasted	Pearl blasted	Pearl blasted	Pearl blasted
Surface finish of the condenser coils	Finish	Cold drawn	Cold drawn	Cold drawn	Cold drawn
Defrosting of ice	Min	40	50	60	60
Ratio evaporator area/shelf area	m² / m²	1	1	1	1
Vacuum					
Final vacuum of the vacuum pump set	mbar	0.005	0.005	0.005	0.005
Final vacuum of the freeze dryer	mbar	0.01	0.01	0.01	0.01
Pump time from 1000 to 0.1 mbar	min	30	30	30	30
Cooling and Heating					
Shelf cooling rate from +20 to -40°C	K/min	1.5	1.5	1.5	1.5
Shelf heating rate	K/min	1.5	1.5	1.5	1.5
Temperature range during drying	°C	-50 - + 60	-50 - + 60	-50 - + 60	-50 - + 60
Condenser cooling rate +20 to -40	K/min	1.5	1.5	1.5	1.5
Final temperature	°C	-75	-75	-75	-75
Performing Data					
Sublimation rate	kg/h	8.33	16.67	25	33.33
Turnaround (CIP, SIP, Drying, Recooling)	h	8	8.5	9	9

Standard and Optional Features – Freeze Dryer

Chamber Rectangular chamber Pressureless vessel Material 316 L Ports 3d Ports 3d Layout 1 Floor 2 Floor Passthrough String Pizza door Automatic locking Pizza door (constant loading level) Oor Condenser Rectangular Rear Side Outor Hydraulic ram coverage with bellow	
Rectangular chamber • Pressureless vessel • Material 316 L • Ports 3d • Ports 3d • Layout • 1 Floor • 2 Floor • Passthrough • • • Door • Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular • Rear • Side • Underneath • Hydraulic ram coverage with bellow •	
Pressureless vessel • Material 316 L • Ports 3d • Layout • 1 Floor • 2 Floor • Passthrough • • • Door • Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular • Rear • Side • Underneath • Hydraulic ram coverage with bellow •	•
Material 316 L Ports 3d Ports 4 Ports	•
Ports 3d • Layout I Floor • 2 Floor • Passthrough • Door Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular Rear • Side • Underneath • Hydraulic ram coverage with bellow •	•
Layout 1 Floor 2 Floor Passthrough Door Full size door Automatic locking Pizza door (constant loading level) Door in door Condenser Rectangular Rear Side Underneath N Hydraulic ram coverage with bellow	•
Layout 1 Floor 2 Floor Passthrough Passthrough Poor Full size door Automatic locking Pizza door (constant loading level) Door in door Condenser Rectangular Rear Rear Side Underneath Hydraulic ram coverage with bellow	
1 Floor • 2 Floor • Passthrough • Door • Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular • Rear • Side • Underneath • Hydraulic ram coverage with bellow •	
2 Floor • Passthrough • Door • Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular • Rear • Side • Underneath • Hydraulic ram coverage with bellow •	•
Passthrough • Door Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular Rear • Side • Underneath • Hydraulic ram coverage with bellow •	0
Door Full size door Automatic locking Pizza door (constant loading level) o Door in door Condenser Rectangular Rear Side Underneath Hydraulic ram coverage with bellow	0
Full size door • Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular • Rear • Side • Underneath • Hydraulic ram coverage with bellow •	
Automatic locking • Pizza door (constant loading level) • Door in door • Condenser Rectangular Rear • Side • Underneath • Hydraulic ram coverage with bellow •	•
Pizza door (constant loading level) Door in door Condenser Rectangular Rear Side Underneath Hydraulic ram coverage with bellow	•
Door in door • Condenser Rectangular • Rear • Side • Underneath • Hydraulic ram coverage with bellow •	0
Condenser Rectangular Rear • Side • Underneath • Hydraulic ram coverage with bellow •	0
Rear • Side • Underneath • Hydraulic ram coverage with bellow •	
Side • Underneath • Hydraulic ram coverage with bellow •	0
Underneath • Hydraulic ram coverage with bellow •	0
Hydraulic ram coverage with bellow	0
	•
CIP	

CIP chamber + condenser	•
Recirculation including heating	0
Multiple cleaning media	0

SIP	
PED	•
ASME	٥
GB-150	٥
Chamber recooling after SIP	•
Hydraulic	
Lift / lower + stoppering	•
Shelf Package	
With rails and fully collapsible	•
Hydraulic ram coverage with bellow	•
Interface for ALUS®	0
Refrigeration	
Piston compressors	•
Screw compressors	٥
Liquid nitrogen	٥
Cascades (propene + ethylene)	0
Vacuum	
Oil sealed vacuum pumps + blower	•
Redundancy (second pump set)	o
Dry pumps + blower	o
Pressure Regulation	
On/Off	•

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Venting System incl. Filter	
Sterilizable	•
Ports for I-Test	•
Second venting media	
Second venting filter	0
Automatic WIT test	0
Control System and Documentation	
PLC Siemens	•
PLC Rockwell automation	0
SCADA - WIN CC	•
Fix	0

PLC Siemens	•
PLC Rockwell automation	0
SCADA - WIN CC	•
iFix	0
Recorder	0
GAMP	•
Audit trail	•
21 CFR Part 11	•
FAT / SAT	•
IQ/OQ Documents and tests	0
Material certificates	0
Wolding documentation	_

Technology

ALUS®	•
ATEX (alcoholic solvent treatment)	0
Cold shelf loading > +5°C	•
Frozen shelf loading < +5°C40°C	•
LYOPLUS®	o
LYOSPARK®	•

Included

Option



Standard and Optional Features – ALUS®

Loading	
Pusher with transfer table	•
Vial handling	•
Tray / nest handling	o
Single row loading	0
Multiple row loading	o
Loading speed 200 V/min	•
Loading speed 400 V/min	o
Loading speed 600 V/min	o
Loading on precooled shelves	•
Transfer cart (automatic)	0
Transfer cart (semi-automatic)	o
Transfer cart (manual)	0
Conveyor belts to the filling machine	•

ontainment	
RABS	•
RABS	•
solator	0

Unloading	
Puller with transfer table	•
Back pusher	•
Vial handling	•
Tray / nest handling	0
Single row unloading	•
Multiple row unloading	•
Unloading speed 200 V/min	•
Unloading speed 400 V/min	•
Unloading speed 600 V/min	0
Transfer cart (automatic)	•
Transfer cart (semi-automatic)	0
Transfer cart (manual)	0
Conveyor belts to the capping machine	•

Cleaning

Wipe down	•
Wet cleaning with spray guns and static rots	0
Inclination of the base plate	0

Technology	
LYODATA®	o
LYOSENSE®	
ATEX	o
Cold shelf loading > +5°C	•
Frozen shelf loading < +5°C40°C	o

IncludedOption





Further information GEA Pharma & Healthcare pharma@gea.com gea.com/contact

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