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# СУШИЛКИ И УСТАНОВКИ ДЛЯ ОБРАБОТКИ ЧАСТИЦ LYOVAC

## Технические характеристики





## Pilot Freeze Dryer LYOVAC® FCM 10-P

The highly flexible standalone FCM 10-P freeze dryer from GEA has been designed for the production of small-scale batches and formulation/process development. Also available as a wall-mounted option, this two-chamber unit is configured to industry standards.

With a capacity of 10 kg and shelf space of 0.63 m<sup>2</sup>, the FCM 10-P also benefits from easy-access doors and spare flanges for validation and/or additional equipment.

Using the same FALCO control system as the production unit, allowing direct recipe transfer during scale-up, the FCM 10-P is GLP/GMP-compliant.

### Available options:

IQ/OQ documentation and test performance

Wireless temperature sensors

Sterilization by VHP (VAPOVAC™) or steam depending on the availability of utilities



- Process development service
- LYOSPARK© controlled nucleation

LYOPLUS© mass spectrometer for silicone oil detection or alternative end-point detection

FCM10-P

|               |                   |
|---------------|-------------------|
| Capacity      | 0,63m² shelf area |
|               | 4 shelves         |
|               | 10 kg in in 24 h  |
| Possible Load | 2608 of 2R vials  |
|               | 1352 of 6R vials  |
|               | 708 of 20R vials  |

# Small Batch Freeze Dryers

For flexible product development and small-scale production. Including the use of nests and tubs, the FCM-I range of LYOVAC® Freeze Dryers from GEA provides reliable, safe and cost-effective productivity and price/performance excellence.

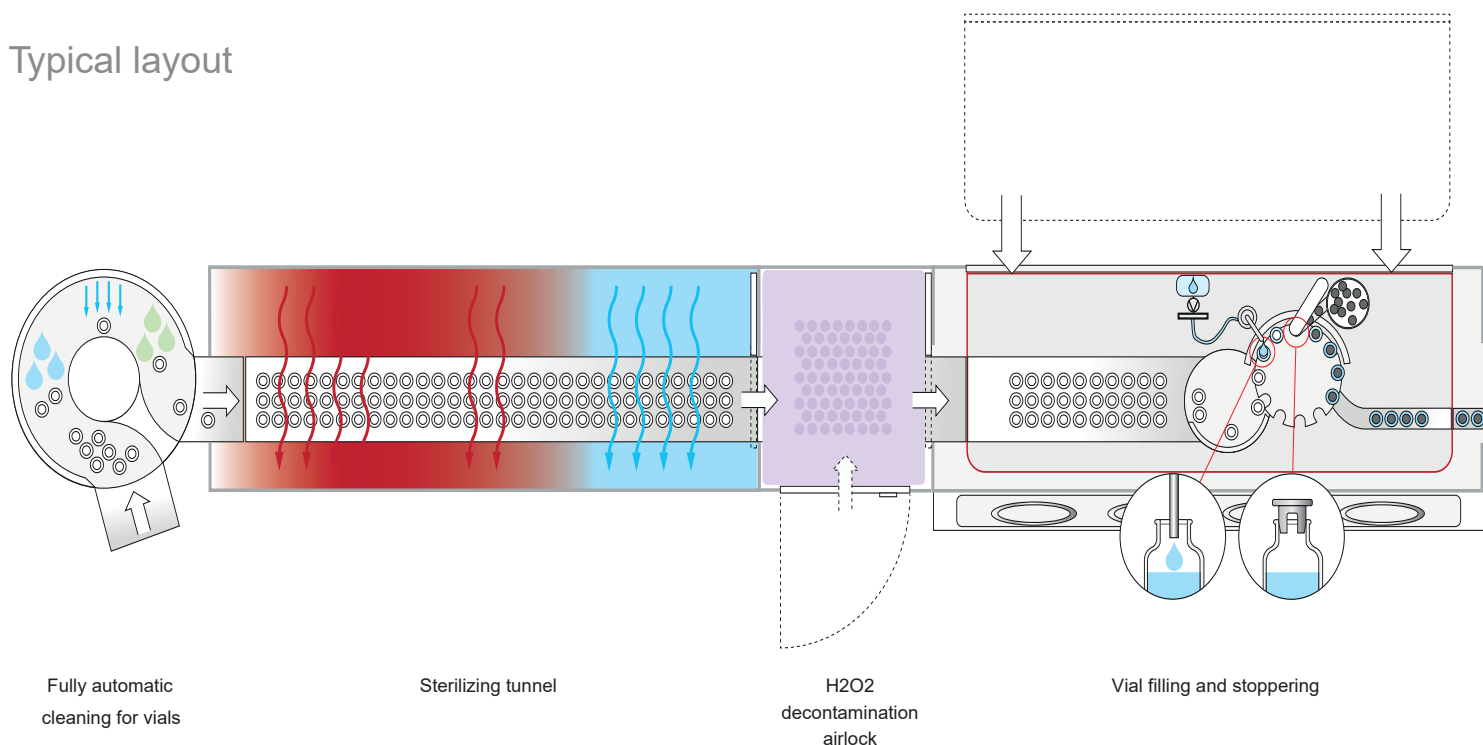
Designed to comply with the most stringent good manufacturing practice (GMP) standards, the LYOVAC® FCM 25-I, FCM 75-I and FCM 150-I freeze dryers are a unique and efficient combination of proven technology and individual solutions that are customized to meet specific user requirements.

## Integrated VarioSys® Isolator

Built with operator safety in mind, full isolator protection for processes involving potent or toxic substances is available, and each unit is supplied with an integrated L-flange for a modular isolator system.

Supplied in three sizes (1.5 m<sup>2</sup>, 4.5 m<sup>2</sup> and 9.9 m<sup>2</sup>) with nominal condenser capacities of 25 kg, 75 kg and 150 kg, the smaller FCM 25-I machine can process up to 6500 vials (2 mL) per batch, whereas the larger FCM 75-I and FCM 150-I units are capable of handling more than 20,000 and 42,000 similarly sized vials, respectively. An automatic loading and unloading system (ALUS®) is available.

## Typical layout



# FCM-I range of LYOVAC® Freeze Dryers



|                      | FCM 25-I | FCM 75-I | FCM 150-I |
|----------------------|----------|----------|-----------|
| <b>Capacity</b>      |          |          |           |
| Shelf area           | 1.5 m²   | 4.5 m²   | 9.9 m²    |
| Shelves              | 5        | 5        | 7         |
| Kg ice/24 h          | 25 kg    | 75 kg    | 150 kg    |
| <b>Possible Load</b> |          |          |           |
| 2R vials             | 6523     | 20,039   | 42,406    |
| 6R vials             | 3388     | 10,506   | 22,295    |
| 20R vials            | 1778     | 5583     | 11,900    |

Operating in a Grade C environment, other modules, such as filling and capping systems, can be quickly and easily interchanged, resulting in both a dramatic reduction in footprint and equipment costs.

Available for rapid delivery — with low infrastructure requirements — for multiple product and/or delivery device lines, the modules offer an ideal solution for vial, ampoule, syringe and cartridge processing, as well as liquid, powder or lyophilized form applications.

The LYOVAC® freeze dryer offer the following features and benefits:

- compact footprint with a belly condenser design
- suitable for Grad C environments
- LYOSPARK® controlled nucleation
- LYOPLUS® silicone oil detection
- Fast turnaround through defrost/CIP/SIP
- alternative end-point detection is also available.

Plus, fully compatible with toxic, potent and volatile products, the FCM units are ATEX-compliant and designed for easy scale-up. Partial loading is also possible for variable batch sizes.



# Technical Data

| Units                            |                | FCM 200            | FCM 400            | FCM 600            | FCM 800            |
|----------------------------------|----------------|--------------------|--------------------|--------------------|--------------------|
| <b>Standard LYOVAC® Models</b>   |                |                    |                    |                    |                    |
| <b>Chamber</b>                   |                |                    |                    |                    |                    |
| Geometry                         | Form           | Rectangular        | Rectangular        | Rectangular        | Rectangular        |
| <b>Shelves</b>                   |                |                    |                    |                    |                    |
| Shelf area                       | m <sup>2</sup> | 10                 | 20.4               | 30.2               | 41.22              |
| No. of shelves                   | Quantity       | 9 + 1              | 11 + 1             | 13 + 1             | 15+1               |
| Shelf size                       | mm             | 914 x 1219         | 1219 x 1524        | 1524 x 1524        | 1524 x 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        |
| <b>Condenser</b>                 |                |                    |                    |                    |                    |
| Geometry                         | Form           | Cylindrical        | Cylindrical        | Cylindrical        | Cylindrical        |
|                                  | Position       | Laterally / behind | Laterally / behind | Laterally / behind | Laterally / behind |
|                                  | Type           | Tube               | Tube               | Tube               | Tube               |
| Nominal ice capacity             | kg             | 200                | 400                | 600                | 800                |
| <b>Chamber \ Condenser Valve</b> |                |                    |                    |                    |                    |
| Type                             |                | Mushroom           | Mushroom           | Mushroom           | Mushroom           |
| Clear diameter                   | mm             | 500                | 700                | 900                | 1000               |
| <b>Weights</b>                   |                |                    |                    |                    |                    |
| Chamber and condenser (empty)    | t              | 12.5               | 15                 | 17.5               | 20                 |

## Utility Consumption

| Units                               |                   | FCM 200 | FCM 400 | FCM 600 | FCM 800 |
|-------------------------------------|-------------------|---------|---------|---------|---------|
| <b>Utilities</b>                    |                   |         |         |         |         |
| 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*                        | m <sup>3</sup>    | 2,6     | 3,4     | 4,2     | 5       |
| Cooling water (Compressor)          | °C                | < 25    | < 25    | < 25    | < 25    |
| Peak flow                           | m <sup>3</sup> /h | 9       | 12      | 15      | 19      |
| Consumption*                        | m <sup>3</sup>    | 138     | 175     | 212     | 267     |
| Electrical power supply             | kW                | 105     | 140     | 175     | 210     |
| <b>Power Consumption per Cycle*</b> |                   |         |         |         |         |
| With compressors                    | KWh               | 650     | 900     | 1250    | 1700    |
| With liquid nitrogen                | KWh               | 140     | 185     | 270     | 305     |
| LN <sub>2</sub> consumption         | kg                | 1610    | 2040    | 3460    | 4030    |

\* Standard cycle

## Base Values

|                                           | Units        | FCM 200       | FCM 400       | FCM 600       | FCM 800       |
|-------------------------------------------|--------------|---------------|---------------|---------------|---------------|
| <b>Chamber</b>                            |              |               |               |               |               |
| Surface finish                            | µm           | 0,8           | 0,8           | 0,8           | 0,8           |
| System leak rate                          | mbar x l / s | 0,008         | 0,008         | 0,008         | 0,008         |
| <b>Shelves</b>                            |              |               |               |               |               |
| 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            |
| <b>Condenser</b>                          |              |               |               |               |               |
| 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             |
| <b>Vacuum</b>                             |              |               |               |               |               |
| 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            |
| <b>Cooling and Heating</b>                |              |               |               |               |               |
| 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           |
| <b>Performing Data</b>                    |              |               |               |               |               |
| Sublimation rate                          | kg/h         | 8.33          | 16.67         | 25            | 33.33         |
| Turnaround (CIP, SIP, Drying, Recooling ) | h            | 8             | 8.5           | 9             | 9             |

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