

LYOVAC[®] SMALL-SCALE FREEZE DRYERS.

For flexible product development and small-scale production.



SMALL BATCH FREEZE DRYERS.

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

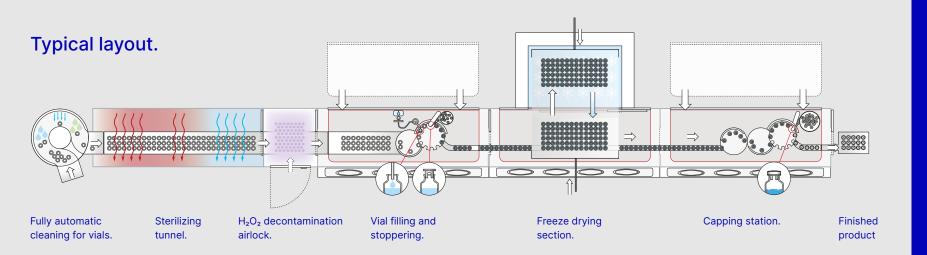
Built with operator safety in mind, full isolator protection for processes involving potent or toxic substances is available,

and each unit is supplied with an integrated L-flange for a modular isolator system.

Supplied in three sizes $(1.5 \text{ m}^2, 4.5 \text{ m}^2 \text{ and } 9.9 \text{ m}^2)$ 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.



LYOVAC[®] FCM-75-I with ALUS[®] for integration in Isolator.



VarioSys®

Since its launch, more than 70 modular VARIOSYS® systems — jointly developed by SKAN AG, Bausch+Ströbel GmbH + Co. KG, GEA, Harro Höfliger Verpackungsmaschinen GmbH and ATEC — have been installed and are currently being used by 30+ biopharmaceutical companies.

FCM-I RANGE OF LYOVAC[®] FREEZE DRYERS.



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.

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.

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





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





GEA Lyophil GmbH Kalscheurener Str. 92 50354 Hürth, Germany

Tel +49 (0) 2233 6999 0 pharma@gea.com gea.com/contact