FREEZE-DRYING SOLUTIONS

Pharmaceutical Lyophilization Technology.

GEA Engineering for a better world.

GEA.com

DELIVERING THE RIGHT SOLUTIONS.

GEA's process expertise is based on a long history of innovation, applied R&D and industry experience

As a long-term partner to the pharmaceutical and biotech industries, our equipment stands for high performance, quality and reliable, trouble-free operation. Every GEA freeze dryer is designed to help our customers to create a product that will succeed in the market — with GEA being a partner in reaching that goal.

Our range of supplies and services includes pilot-scale freeze dryers for R&D purposes and small production batches, industrialscale freeze dryers and completely integrated systems, including Automatic Loading and Unloading Systems (ALUS®) and CIP skids. In addition, the company services and retrofits existing freeze dryers.

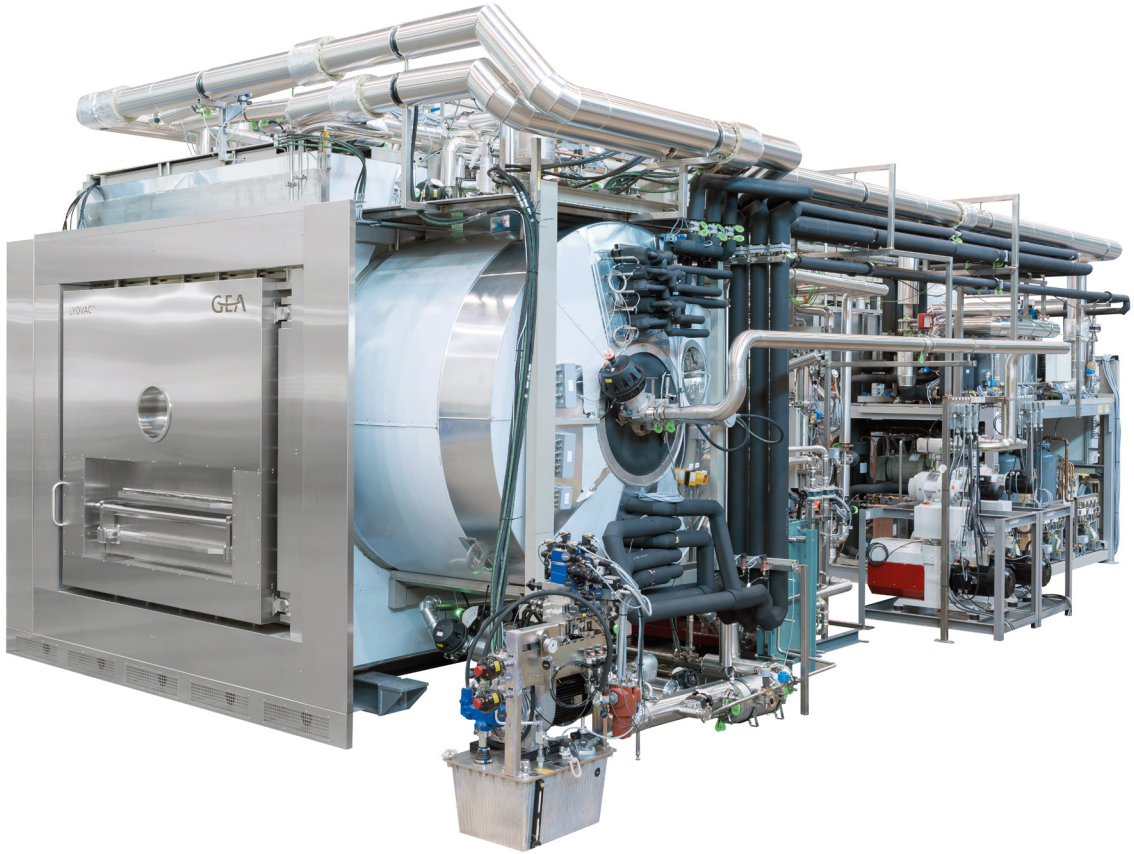
The design and manufacture of freeze dryers and freeze-drying systems is done in accordance with all relevant guidelines, such as GMP, GAMP5 and 21 CFR Part 11, as well as other worldwide regulatory requirements, such as CE, UL, ASME, BPE and PBD.

The company's expertise in freeze drying and related processes — isolator technology, sterilization and clean-in-place (CIP) — covers all kinds of pharmaceuticals and biotechnology derived products, such as hormones, vaccines, antibiotics anti-infectives, bacteria, sera, enzymes, diagnostic agents, monoclonal antibodies (mAbs) and blood products.

And, with more than 250 validated ALUS® installations, worldwide, we have an unparalleled history of innovation for various pharmaceutical applications that demonstrate our capability.

FREEZE DRYING ESSENTIALS.

Freeze drying (lyophilization) has a key role to play in aseptic pharmaceutical and biotech production as fill and finish process.



From its earliest applications in the stabilization of blood plasma, freeze drying has been in use in the life science industries for more than 50 years. During this period, the freeze dryer — or lyophilizer — has evolved from a simple device for vacuum drying at low temperature to an extremely sophisticated integrated system that combines a number of processes to ensure that a product is consistently delivered to technical and biological specifications while also considering economic, safety and environmental issues.

Freeze drying is a dehydration process typically used to preserve a perishable material or make the material more convenient for transport or storage. Freeze drying works by freezing the material and then reducing the surrounding pressure to allow the frozen water in the material to sublimate directly from the solid phase to the gas phase.

Generally, the freeze drying process is done in three steps, under vacuum: freezing, primary and secondary drying. The product to be dried is frozen under atmospheric pressure. Then, in an initial main or primary drying phase, water, in the form of ice, is removed by sublimation; in the secondary drying phase, it is removed by desorption. The reduced moisture content improves the stability and shelf-life of the product; but, in some instances, rehydration can further improve those properties.

The fourth step, rehydration, can be implemented after the secondary drying phase. During rehydration, low concentrations of moisture are intermittently added to the chamber until the required moisture content of the product has been reached. The length of the rehydration phase is product- and moisture content-dependent.

Further information
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