GEA ASEPTIC-SD®

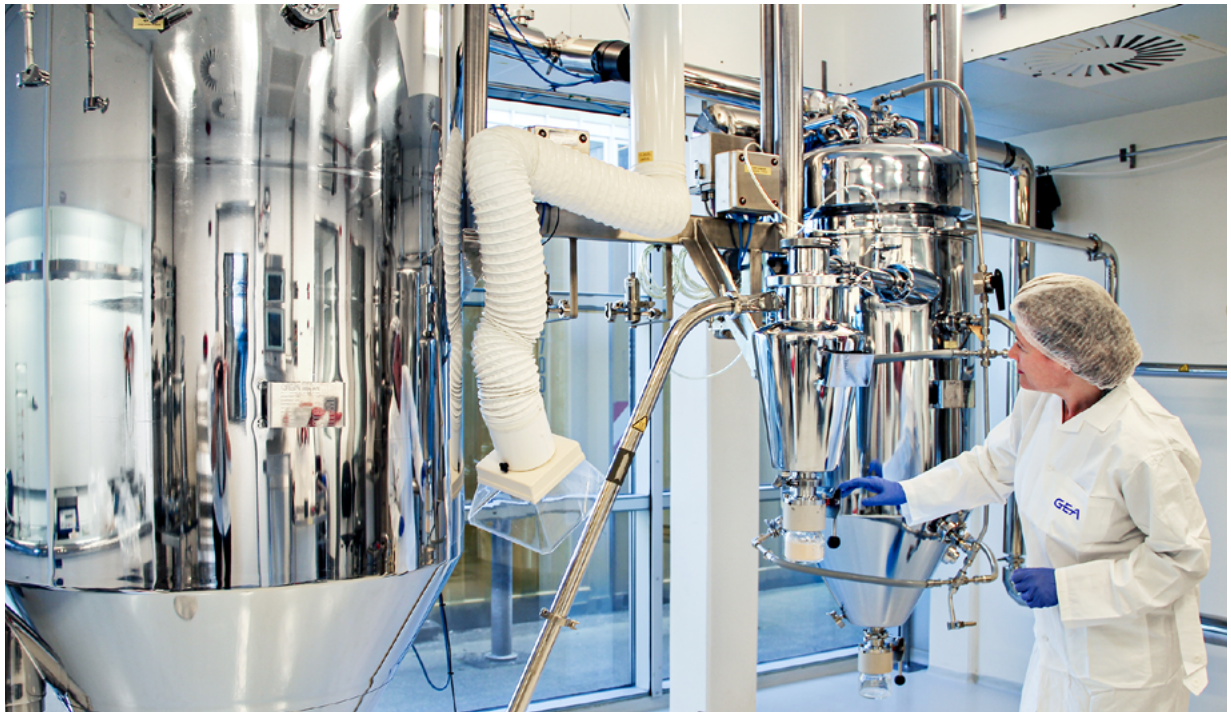
Aseptic spray dryers for sterile pharma applications.

GEA Engineering for a better world.

GEA.com

ASEPTIC SPRAY DRYING TECHNOLOGY.

Tailored for pharmaceutical applications, giving you the freedom to formulate sterile powders for injection.



High performance spray dryers for sterile (bio) pharmaceuticals.

The GEA ASEPTIC-SD® aseptic spray dryer for pharmaceutical applications is built on decades of GEA expertise developing and installing more than 10,000 spray drying systems for multiple industries around the world. We've combined our process, engineering and technology knowhow with detailed pharmaceutical industry insight and experience to give you a safe and reliable aseptic technology for the most exacting pharmaceutical powder applications. The GEA system offers top performing spray drying for producing sterile biotherapeutics and small molecules that have precisely defined particle properties, and which can be easily reconstituted for injection or parenteral administration.

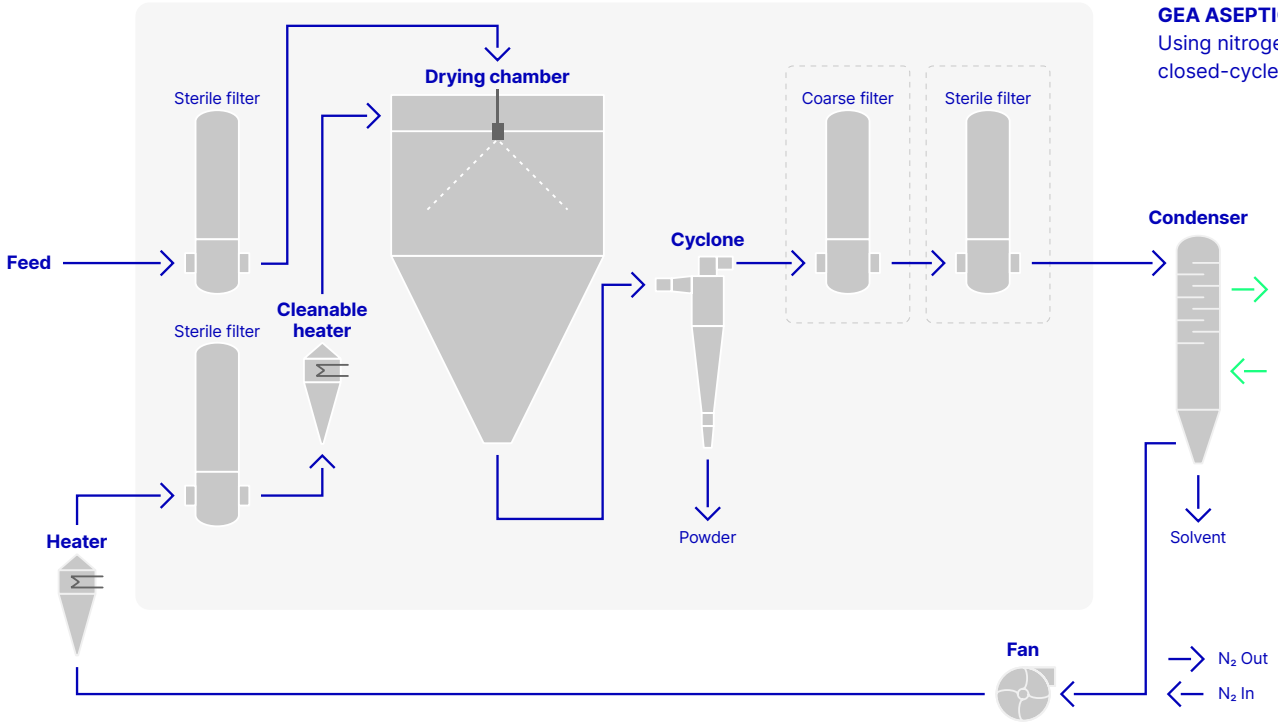
Preferred technology for powdered pharmaceutical formulations.

Over the past three decades, spray drying has emerged as the preferred technology for producing powder formulations with defined critical quality attributes. Small molecule active pharmaceutical ingredients (APIs), combined with excipients, typically in organic solvents are more commonly spray dried than freeze dried. Spray drying can be an ideal solution for producing small molecule compounds as well as biotherapeutics. The resulting spray dried dispersions (SDD) most often exhibit enhanced bioavailability compared with conventional powder formulations.

The benefits of spray drying compared with freeze drying may include:

- Particle engineering to control powder physical properties (particle size, shape, density)
- Powder with increased surface area and dissolution rate
- Organic solvent evaporation and easy solvent recovery on larger aseptic spray dryers
- No frozen state, stable powder without salts or cryoprotectants
- Simplified scale-up
- Continuous process with rapid drying times
- Minimal plant footprint
- Lower capital investment
- Reduced running costs (lower energy consumption)

Advantages of spray drying.



GEA ASEPTIC-SD®
Using nitrogen in closed-cycle set-up.

Spray drying can offer numerous advantages when compared with freeze drying (lyophilization), which has traditionally been used to dry large molecules – commonly biologics - in aqueous solutions. When compared with freeze drying, spray drying becomes more cost effective the higher the throughput, and a single GEA ASEPTIC-SD® spray dryer might replace several large lyophilizers, significantly reducing investment and running costs as well as simplifying plant operation.

Enabling aseptic spray drying.
While retaining the features and technology of our standard pharmaceutical spray dryers, our aseptic spray dryers incorporate an advanced cleaning system, steam sterilization capabilities, multiple sterile filters, and a filter integrity testing before and after aseptic processing.

A comprehensive portfolio of pharmaceutical spray and freeze dryers.
When aseptic processing isn't required, the GEA PHARMASD® (PSD) portfolio of pharmaceutical spray dryers offers a range of different sizes and capacities that have set the benchmark in pharma spray drying and are widely adopted by pharma companies globally. The GEA ASEPTIC-SD® aseptic spray dryer allows customers to harness that proven PSD technology to engineer the particle properties of aseptically produced powdered (bio)pharmaceuticals. The PSD and aseptic pharmaceutical spray drying systems are available alongside our recognized pharmaceutical freeze dryers, so customers can select the optimum drying technology, and process setup for their pharmaceutical and biotech products.

Seamless transfer from a non-sterile to a sterile process.
The GEA ASEPTIC-SD® spray dryer models are supplied in the identical sizes and capacities as our standard PSD pharmaceutical spray dryers. The aseptic units are also built on the same design and have the same chamber geometry as the PSD models. This facilitates efficient process transfer from non-sterile to sterile spray drying and keeps associated setup time and cost as low as possible.

This physical equivalence between our systems means that process data obtained during R&D at preclinical stage can be used to successfully develop a robust, regulatory-compliant process for producing sterile powders for clinical trials and commercial production.

Sterile filter arrangement
For inlet process gas.

Can heat-sensitive biologics be spray dried?

During spray drying, the product is briefly exposed to hot gas temperatures above 100°C, but evaporative cooling ensures that the product remains below this temperature range – typically set at 60°C to 80°C, and sometimes lower, especially for non-aqueous feeds. This brief exposure, lasting a few seconds, ensures product integrity and activity retention. In several cases, spray-dried products have exhibited superior activity compared to freeze-dried counterparts, attributed to reduced stress from phase changes during freezing and shorter residence times in spray dryers.

A wide range of end products

Example of sterile products that can be dried with the GEA ASEPTIC-SD® pharmaceutical spray dryer:

- Monoclonal antibodies
- Therapeutic peptides and proteins
- Vaccines
- Hormones
- Allergens
- Blood products
- Powders for parenteral infusions
- Antibiotics

GEA test centers for evaluating and optimizing aseptic spray dryers.

At our drying test center in Denmark, GEA specialists in pharmaceutical spray drying can work with you to devise the optimum system for your process and products, looking at every detail, including your existing setup and budget. We can offer you full spray drying support, from drying kinetics studies on a single droplet to evaluate possible feed formulations, to feasibility tests, and scale-up. Then, it will be relatively simple to transfer the process design developed on our technical pilot plant to your new GEA ASEPTIC-SD® dryer.

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