

Aseptic Spray Dryers

An effective method for
sterile solid drug manufacture



Aseptic spray drying – an exciting development

For expensive sterile drugs shelf-life is of the essence. The traditional way to convert a sterile liquid into a stable solid form is freeze drying (lyophilisation), but there is now an alternative. Spray drying has for decades been used within the pharmaceutical industry for producing powders – also under aseptic conditions. The new generation of GEA Niro Aseptic Spray Dryers – ASEPTICSD™ – makes a compelling case, as detailed below.

Well-accepted sterilisation procedure

Sterilisation using pure steam is the preferred and proven method within the pharmaceutical industry. For complex designs and where the product is in contact with the equipment surface, air pockets must be removed by applying vacuum. These challenging requirements are met by the new generation of GEA Niro Aseptic Spray Dryers (patents pending).

Heat sensitive compounds can be spray dried

Vaccines, antibiotics, hormones and allergens are all examples of spray dried products. During spray drying, the hot gas entering the drying chamber is often well above 100 °C. But because of evaporative cooling, the active drug is only exposed to temperatures below that of the exhaust gas – commonly set at 60 °C to 80 °C, and sometimes lower, particularly for non-aqueous feeds. This exposure lasts for just a few seconds before the powder is discharged, which means the active ingredients are not damaged. The activity of the spray dried product has in several cases proven to be better than when the same product is freeze dried – e.g. because of stress created by phase changes during freezing or the 48-hour freeze drying process versus the short residence time in a spray dryer.

A homogenous powder

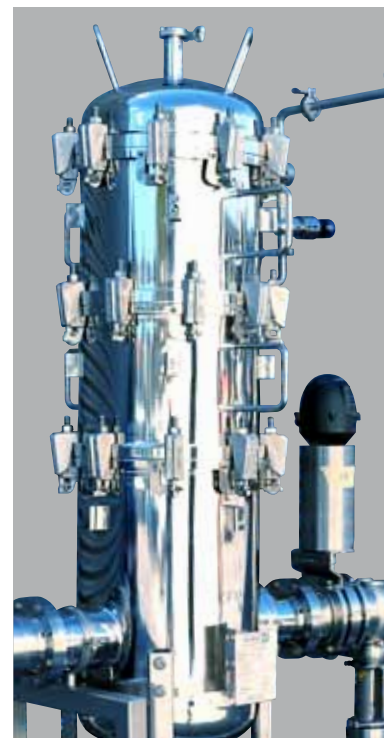
By selecting the appropriate plant design and operating conditions it is possible, in a single process step, to produce a free-flowing powder comprising either single particles or controlled agglomerates for filling syringes, vials or implants. Many sterile liquid feeds originate from biological processes in which the drug activity per volume varies from batch to batch. Also, during drying the drug activity may be altered to different degrees. Spray drying produces a homogenous powder, so determining the activity of the powder allows you to accurately fill the correct “amount of activity” in your vials.

Formulation freedom

As in freeze drying, the formulation of a feed suitable for spray drying focuses on how to stabilise and improve the effectiveness of the API – but without the added complexity of considering freezing characteristics. Spray dryers are also designed for handling organic solvents, which makes possible the use of a wide range of excipients within the formulation.

High capacity and lower costs

Spray drying is a continuous, scalable and well proven technology, with plant capacities from 10's of grammes to 10's of tonnes per hour. When compared to freeze drying, the higher the throughput the more advantageous spray drying becomes, as a single GEA Niro Aseptic Spray Dryer can replace six to eight large lyophilizers, thus significantly reducing investment and running costs as well as simplifying plant operation.



Sterile filter arrangement for inlet process gas

The bottom of the spray drying chamber and top of the cyclone are placed in a technical area





Sterile powder from the cyclone is discharged in a clean room



Detail from the exhaust filter arrangement

Spray drying ideal for low bio-burden intermediates

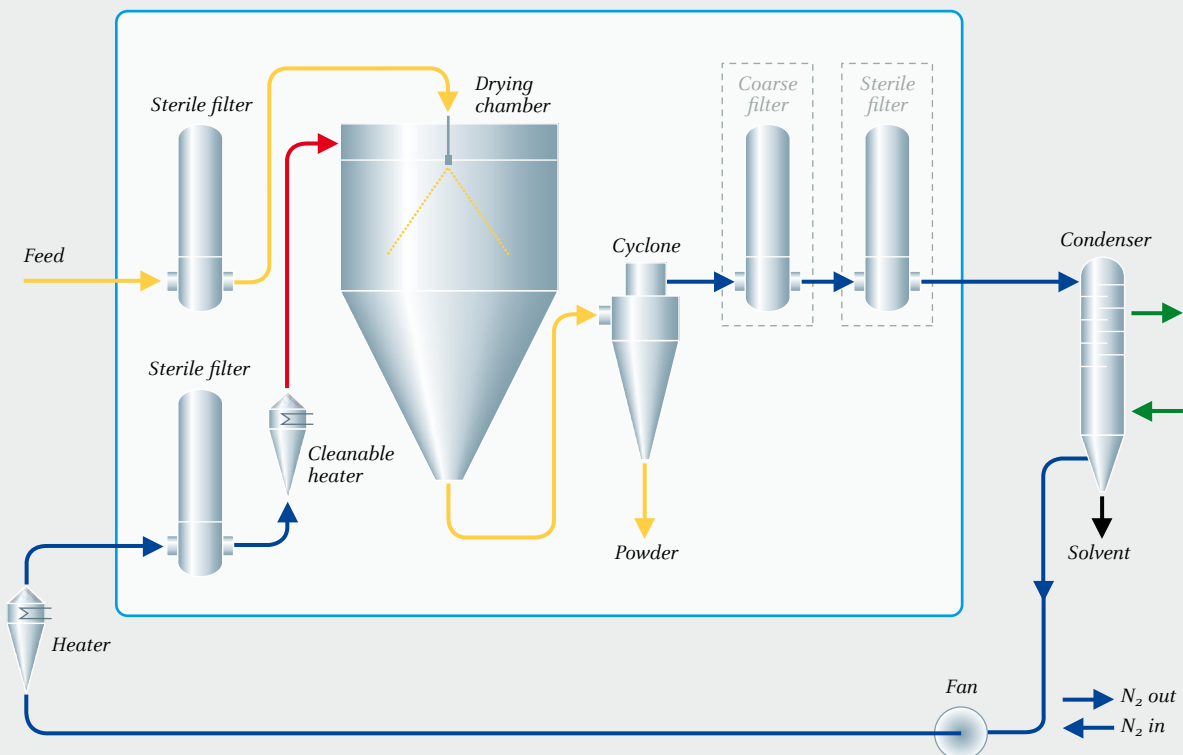
Whenever possible, guidelines call for products to be terminally sterilised. In such cases, there is no need for an aseptic spray drying process, but the plant design must ensure a low bio-burden. Here GEA Niro's other GMP spray dryers offer a cost-effective solution.

From R&D to commercial production

GEA Niro has several test facilities around the world. In the GEA Niro Test Centre in Copenhagen, Denmark, we 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 is simple to transfer the process from our technical pilot plant to your GEA Niro Aseptic Spray Dryer.

GEA Niro Aseptic Spray Dryers – ASEPTICSD™ – have the same wide range of possibilities for capacity, powder engineering, batch size flexibility, etc., as conventional spray dryers.

Aseptic Spray Dryer – ASEPTICSD™ – using nitrogen in closed-cycle set-up





Experience

GEA Niro has contracted and installed more than 10,000 plants worldwide

GEA Niro is a world leader in industrial drying, with spray drying, spray cooling/congealing, flash drying, freeze drying, granulation and fluid bed processing as core technologies. Having installed more than 10,000 plants around the globe, GEA Niro is known for delivering solutions that meet customers' exact requirements. The GEA Niro companies are part of the Process Engineering Division of the GEA Group.



GEA Process Engineering Inc. • 9165 Rumsey Road • Columbia, MD 21045
Tel: 410-997-8700 • Fax: 410-997-5021 • Email: gea.pe.na@geagroup.com
GEA Process Engineering Inc. • 1600 O'Keefe Road • Hudson, WI 54016
Tel: 715-386-9371 • Fax: 715-386-9376 • Email: gea.pe.na@geagroup.com
Web: www.niroinc.com