GSX – SPRAY DRYING

Engineered with pharmacists for pharmacists

Integrated Process Solutions.

Engineered for pharmacists

Our spray drying solutions are developed together with pharmacists, delivering precise particle engineering as well as required product properties with Glatt´s well-known GMP design. From early formulation development to commercial manufacturing, we enable safe processing of even highly potent APIs, seamless digital control and a clear, reproducible scale up from lab to production.

- Engineered with pharmacists for pharmacists
- Flexible air distributor for different process gas flows and atomizers
- Full GMP design for pharmaceutical products
- Dedicated particle collection for your application
- Handling of high potent drugs up to OEB 5
- The only lab spray dryer with FDA CFR 21 Part 11-compliant, production-scale SCADA system as standard
- Clear scale-up concept

Engineered particles – based on your pharmaceutical applications

Spray drying is particularly suitable in situations where liquid media like suspensions or solutions need to be converted into stable solid products. For example, to improve the bioavailability of pharmaceutical active ingredients or to stabilize sensitive nutritional supplements.

Formulations that can be processed via spray drying include, but are not limited to amorphous solid dispersions, nanocrystals, and lipid-based drug delivery systems (e.g. SEDDS, liposomes, etc.).

For you as a user, this means additional options in process design and more flexibility in particle design when existing methods reach their limits.

Oral Solid Dosage Forms
Glucagon-Like-Peptide-1 against diabetes, which is normally applied as an injection, can be powderized and compressed into an oral tablet for optimized patient compliance

Inhalation & Nasal Application
Anti-asthma or nose-to-brain medicaments (i.e. hypnotics) can be inhaled as small powder particles in a minimized dose to significantly reduce side effects

Micro-/Nanonization
Efficiency of drugs providing a very low bioavailability (i.e. BCS IV) can be highly improved by creating a powder (dry suspension) throughout spray drying process

Microencapsulation
Volatile oils can be stabilized and taste masked by spray drying or spray congealing to prolong shelf life and improve palatability

Biopharmaceuticals & Biologics
For aseptic manufacturing of e.g. moisture sensitive therapeutic proteins like Insulin & vaccines in the form of powders for reconstitution to be stored in vials or pre-filled syringes

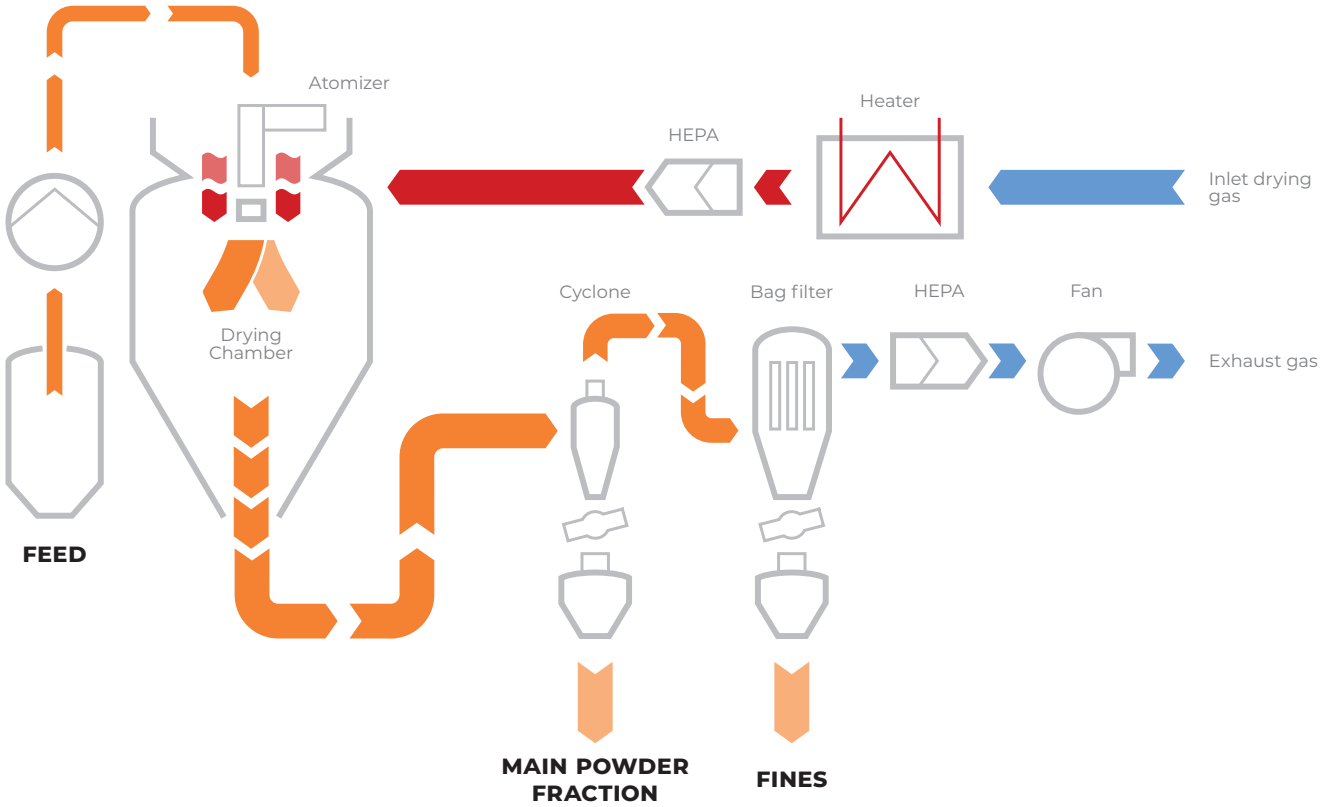
The spray drying process

Spray drying is a continuous process that converts liquid feed into a fine dry powder by rapid evaporation with hot air. Inlet drying gas is heated, filtered and introduced into the drying chamber, where it meets the liquid feed – such as a suspension, solution or an emulsion. The feed is atomized through a nozzle or rotary atomizer into fine droplets. This atomization step is essential, as it creates a large surface area that enables fast and efficient evaporation.

As the droplets come into contact with the hot process gas, they transform into solid particles, resulting in a fine powder and are transferred out of the drying chamber with the airflow.

The air–powder mixture then enters a cyclone, where the particles are separated and discharged as the final product. Remaining fine particles are captured in a bag filter and can be recovered. The cleaned air passes through a HEPA filter and is exhausted by a fan.

For organic solvents, a closed-loop system with a condenser is used to recover the solvents and recycle the Nitrogen in a Solvent Recovery System (SRS).



The right atomization method for every particle

Selecting the right atomization method is a key design decision in spray dried particle engineering, as it directly influences drying efficiency, particle size distribution and product properties. Glatt offers a broad portfolio of atomization solutions to precisely meet the required particle design and product properties.

Two-fluid top spray nozzle

In the two-fluid top spray nozzle, atomization is achieved through the interaction of compressed gas with the liquid feed stream. At the nozzle tip, the liquid is finely dispersed by the compressed gas leading to the formation of uniformly sized droplets. As the droplets come into contact with the hot process gas, they transform into solid particles, resulting in a fine powder. The particle size can be precisely controlled by adjusting the ratio between the atomizing gas pressure and the liquid feed at the nozzle. This two-fluid nozzle atomizing principle is particularly advantageous for drying heat sensitive and very fine powders with a brought particle size distribution. It supports a wide range of throughputs to meet varying production demands. In addition, the nozzle design allows for quick assembly and disassembly, ensuring straightforward maintenance and efficient cleaning.

Pressure top spray nozzle

The pressure top spray nozzle atomizes liquid by converting pressure energy into kinetic energy as the liquid is forced through a small orifice. This creates a thin liquid film that breaks up into fine droplets, resulting in a controlled and efficient atomization process.

Droplet size can be precisely adjusted by varying the inlet pressure and nozzle size. Pressure nozzles are characterized by a relatively narrow droplet size distribution and tend to produce coarser free flowing powders compared to two fluid nozzles. They are also designed for easy installation and quick replacement, ensuring simple handling and low maintenance effort.

Two-fluid fountain spray nozzle

In the two-fluid fountain nozzle atomization process, atomization is achieved through the interaction of compressed gas with the liquid feed stream. The droplets from the fountain nozzle stream from bottom-up whilst the process gas is entering the drying chamber from top-down. When both streams meet, the droplets come into contact with the process gas, they transform into solid particles, resulting in a fine powder.

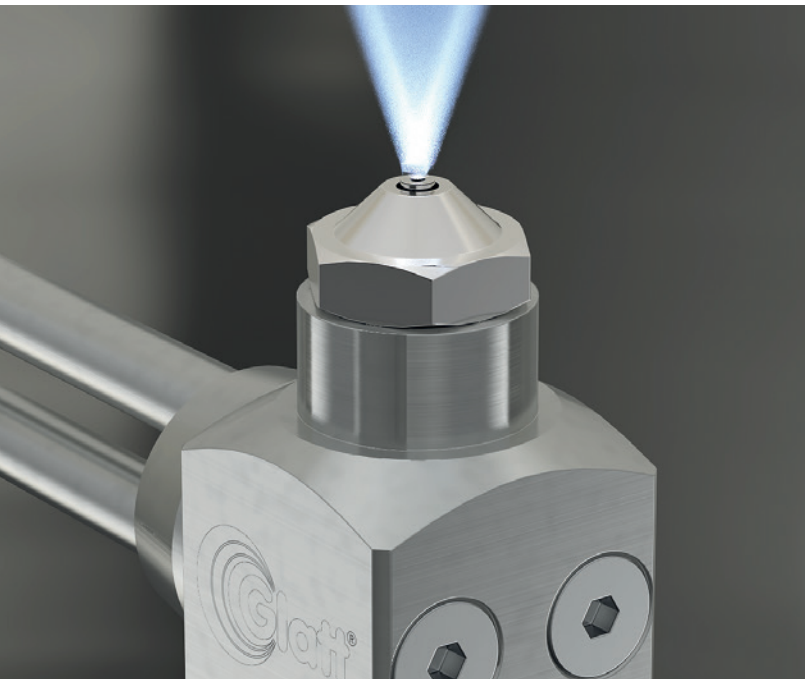
The particle size can be controlled by adjusting the ratio between the atomizing gas pressure and the liquid feed at the nozzle. This provides a high degree of process flexibility and allows the system to be adapted to a wide range of product specifications.

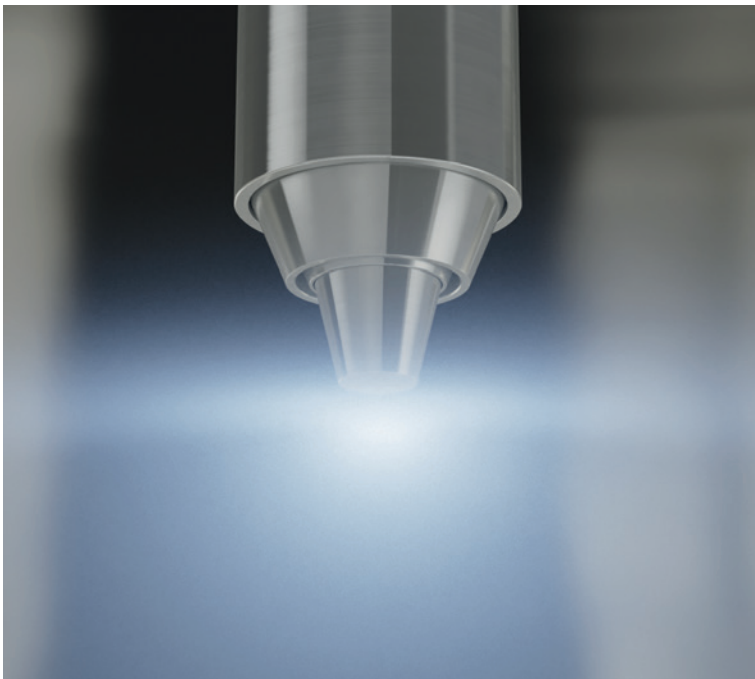
A fountain nozzle configuration is typically used for spray congealing. Fountain nozzles are usually not recommended for heat sensitive products. In addition, the nozzle design allows for quick assembly and disassembly, ensuring straightforward maintenance and efficient cleaning.

Rotary atomizer

In rotary atomization, the liquid feed is dispersed by centrifugal force using a high speed rotating wheel. As the liquid is accelerated at the atomizer periphery, it is finely sprayed into the hot process gas, enabling rapid and efficient drying. Particle size is mainly controlled by the atomizer design, wheel speed, feed rate and liquid properties.

Rotary atomizers are highly flexible and well suited for high viscosity feeds. They support high throughput and produce powders with a narrow particle size distribution and good flowability. The GMP compliant design, combined with quick assembly and disassembly, ensures easy cleaning, efficient changeovers, and reliable operation in regulated production environments.





Advanced processing technologies

Application-specific air distribution for optimal process control

The air distributor is responsible for introducing a homogeneous and well-defined airflow into the drying chamber. Glatt provides application-specific air distributors tailored to different atomization systems, ensuring optimal process conditions. By precisely shaping and balancing the airflow, the air distributor enables stable spray patterns and efficient heat and mass transfer, resulting in consistent drying performance. Its design supports accurate adjustment of airflow rates. The result is reproducible particle formation, high process stability and precise control of critical parameters. The design of the air distributor ensures that the droplets efficiently come into contact with the hot process gas and rapidly transform into solid particles, resulting in a fine powder. The evaporation keeps product temperatures low despite high inlet air temperatures, protecting heat-sensitive products. The GMP design of the air distributor ensures full drainability for effective cleaning and hygienic operation.

Efficient cyclone technology for consistent performance

Efficient, reliable powder separation is critical to spray drying performance. Glatt's cyclone technology delivers consistently high separation efficiency while minimizing common issues such as powder settling, smearing, abrasion and milling effects. Optimized airflow and smooth, hygienic geometries ensure high powder recovery – even for fine and low-density particles. The result: higher yields, reduced losses, and a more economical drying process.

DIFFERENT CYCLONE SIZES AVAILABLE

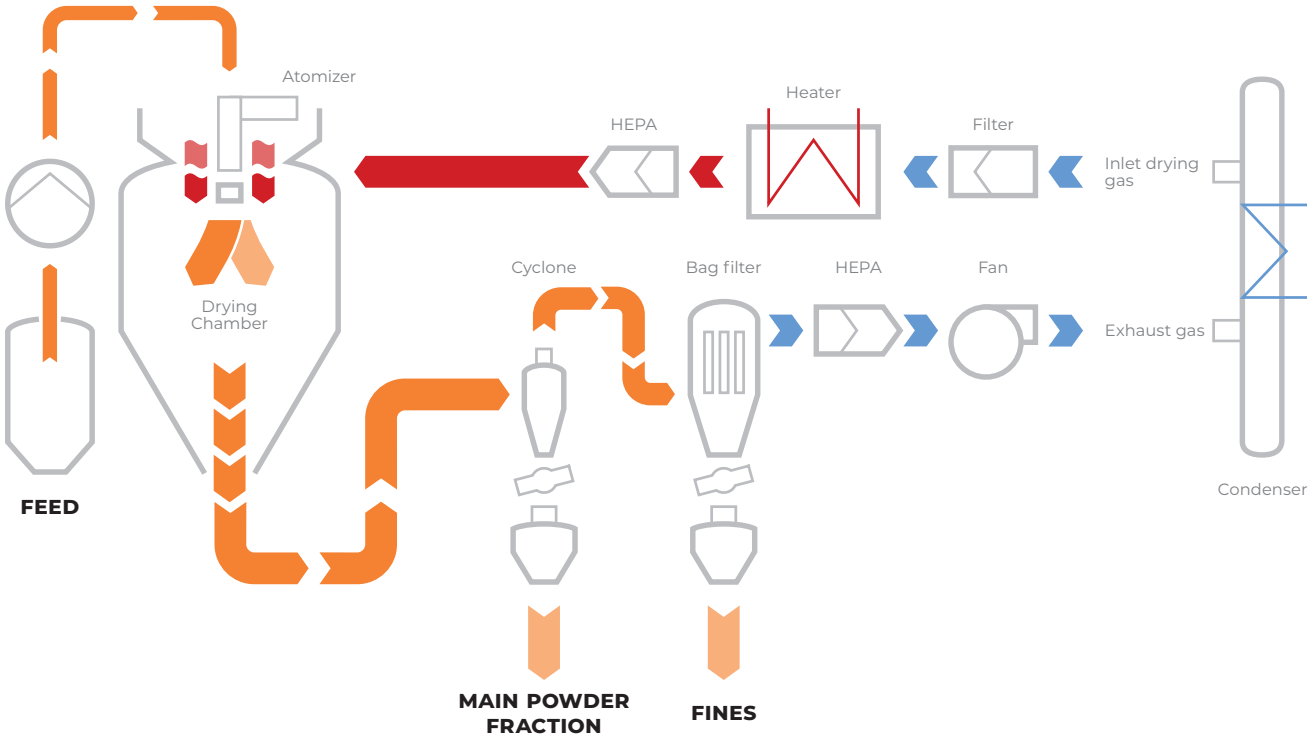
High-efficiency filtration for maximum powder recovery

The Glatt bag filter is designed for maximum particles recovery, collecting powder either from the cyclone or alternatively directly from the spray drying chamber. Filter materials are developed by Glatt and are manufactured in-house in compliance with strict GMP requirements in accordance with FDA and EU regulations as well as ATEX safety standards. Equipped with highly efficient blow-back cleaning system, the Glatt filter bag ensures maximum powder collection and continuous operation. During operation, compressed air is periodically blown in the opposite direction of the normal filtration flow, removing dust particles from the filter surface and maintaining consistently high filtration efficiency. As an alternative to textile filter media, Glatt also offers interchangeable stainless steel filter, ideally suited for cleaning-in-place (CIP) applications. The recovered powder is collected in the cone section beneath the filter housing. With its unique blow-back system, the filter housing meets the highest standards for GMP compliance, cleanability and process reliability.

Solvent Recovery System (SRS)

Our Pharma spray drying technology with integrated containment follows a fully closed process design. Product feeding, atomization, drying, powder separation and discharge are performed without open interfaces. High efficiency cyclones, secondary filters and defined pressure regimes ensure secure separation of particles while preventing product release into the surrounding area.

The use of inert process gases such as nitrogen further enhances safety when processing organic solvents or protecting oxygen sensitive products. Continuous monitoring of oxygen levels and system pressure guarantees stable and controlled operating conditions throughout the entire spray drying process.



Control systems – one concept from lab scale to production

Glatt offers customized control systems that ensure safe, efficient, and reliable operation of spray drying systems across all pharmaceutical scales. All control systems are developed and manufactured in-house using globally established software and hardware, guaranteeing long-term availability and full regulatory compliance.

Based on the intuitive, SCADA-based GlattView operating concept, the systems provide clear visualization and user-friendly interfaces for simple and safe operation, even for demanding processes. GlattView is available from laboratory-scale spray dryers to full production plants, enabling straightforward scale-up and seamless transfer of process data and recipes from early trials to commercial production. The recipe-based control logic ensures clearly defined production conditions, consistent product quality, and reproducibility at all times. The well-proven GlattView control system is FDA CFR 21 Part 11 validated and can be seamlessly integrated into customer-specific digital environments, including ERP, MES, and cloud-based solutions, supporting future-ready and compliant pharmaceutical manufacturing.

Containment in pharmaceutical spray drying

In pharmaceutical spray drying, containment is not an option – it is a requirement. When handling highly potent or solvent based formulations, reliable containment concepts are essential to ensure operator safety, product integrity and full regulatory compliance.

Our pharmaceutical spray dryers are therefore designed as closed systems that enable safe processing from feeding to powder discharge. Continuous containment across all critical process steps minimizes exposure risks while ensuring reproducible product quality in regulated GMP environments.

Integrated containment across the entire system

Reliable containment in spray drying cannot be achieved by individual components alone. It requires a holistic system concept:

- → Gas tight connections between all process modules
- → Defined filtration concepts for exhaust and recirculation air
- → Containment interfaces for powder charging and discharging
- → Containment oriented design of sampling, cleaning and maintenance interfaces

This integrated approach ensures that containment performance is maintained not only during production, but also during cleaning, product changeover and service operations – critical moments for operator exposure.

Cleaning concepts that support containment

Cleaning is an integral part of any pharmaceutical spray drying process – and a critical phase from a containment perspective. Closed pre-wash concepts reduce the risk of airborne particles before system opening, thereby significantly lowering exposure risks for operators. Further advanced Clean-in-Place (CIP) systems further eliminate exposure level before opening the spray dryer.

Design principles focused on cleanability, accessibility and reproducibility enable safe manual or automated cleaning procedures in line with GMP requirements.

This supports fast product changeovers, validated cleaning results and long term operational safety.

Designed for GMP environments

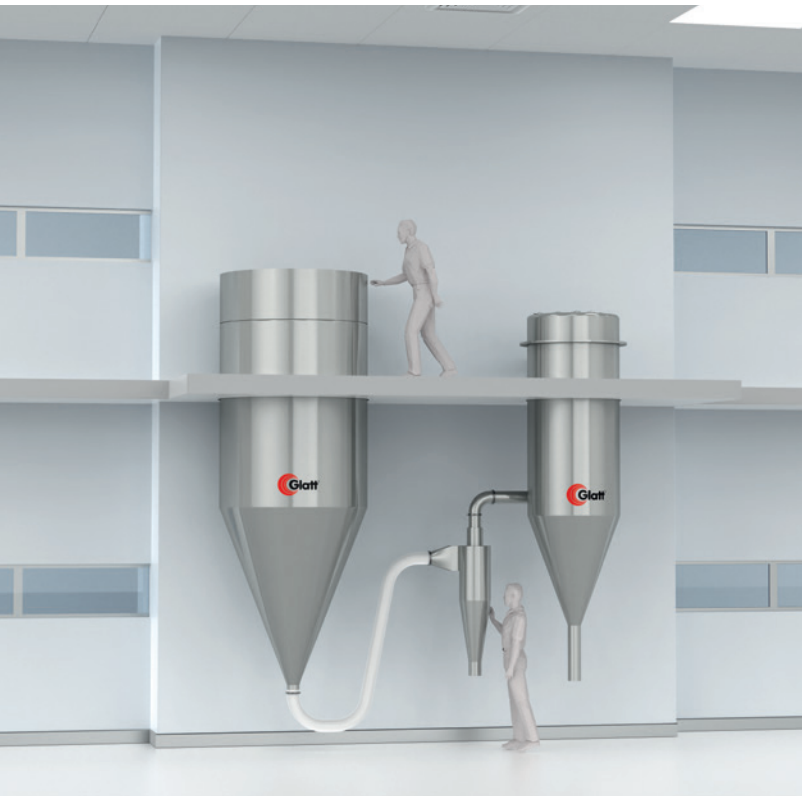
Containment ready spray drying systems are developed for installation in controlled pharmaceutical environments with defined air exchange rates, pressure cascades and monitoring concepts. Combined with validated containment performance, this ensures:

- → Protection of personnel when handling potent substances
- → Prevention of cross contamination between products
- → Full compliance with GMP and occupational safety regulations

The result is a spray drying solution that combines high process performance with maximum safety – from early development to commercial production.

Seamless scale-up from lab to commercial production

With the Glatt Spray Dryer scale-up philosophy, lab-developed formulations are seamlessly translated into reliable, commercial-scale spray drying processes. Backed by 75 years of experience in the pharmaceutical industry, Glatt provides expert support to ensure consistent product quality and full regulatory compliance for your spray drying processes.



Flexible, GMP-compliant cleaning concepts for reliable production

Glatt spray dryers are designed with a highly efficient and application oriented WIP (Wash-in-Place) and CIP (Clean-in-Place) cleaning concept, ensuring reliable cleanliness while minimizing manual effort, downtime, and operator exposure – fully aligned with GMP requirements.

Glatt spray dryers are designed with a highly efficient and application oriented cleaning concept, ensuring reliable cleanliness while minimizing manual effort, downtime, and operator exposure – fully aligned with GMP requirements.

Depending on product characteristics and regulatory requirements, different cleaning approaches can be implemented – precisely tailored to each application:

- **For simple applications, targeted manual rinsing of the drying chamber may be sufficient.**
- **For more demanding products benefit from enhanced mechanical cleaning, such as the use of orbital cleaners instead of standard atomization devices. Strategically positioned CIP cleaning nozzles ensure effective wetting and cleaning of all surfaces in contact with product.**

Glatt enables automated and reproducible WIP or CIP (Clean-in-Place) cleaning procedures with minimal disassembly efforts.

This is supported by hygienic design features such as optimized chamber access, integrated cleaning nozzles and components specifically developed to minimize dead zones and product residues:

- **In the Glatt small scale spray dryers, ducts and main components are typically connected via clamp connections, allowing fast disassembly and efficient manual WIP cleaning.**
- **In large-scale production systems, a semi-automatic or automatic cleaning is recommended. To increase cleaning efficiency and process robustness, the spray dryer can be segmented into defined cleaning zones, which are activated individually via the GlattView controls system. This zoned concept allows targeted cleaning of specific system sections, reducing unnecessary exposure of non critical areas.**

  As a result, cleaning time, water and media consumption and operator intervention are significantly reduced, while a consistent, reproducible and fully GMP compliant cleaning outcome is maintained.

Aseptic spray drying – expertise you can trust for sterile pharmaceutical applications

Glatt offers comprehensive in-house expertise for aseptic spray drying solutions tailored to the highest pharmaceutical requirements. Our approach is designed to ensure maximum product safety, process reliability, and regulatory compliance.

The aseptic spray drying concept is based on steam sterilization under pressure, enabling reliable sterilization of the complete system prior to production. This ensures a controlled, aseptic process environment that meets regulatory guidelines for the manufacture of sterile sensitive pharmaceutical products.

By combining the Glatt GSX spray drying technology with validated sterilization concepts and deep pharmaceutical know-how, Glatt can on special demand deliver aseptic solutions for demanding applications – from development to commercial production.

Process Analytical Technology (PAT) in pharmaceutical spray drying

Process Analytical Technology (PAT) brings real-time transparency to pharmaceutical spray drying.

By continuously monitoring critical process parameters and quality attributes such as particle size, moisture and temperature, PAT enables immediate detection of deviations and rapid process control.

Glatt offers PAT systems which are suitable for spray drying and can integrate PAT on customer demand.

Test facility – From first idea to reliable production

Developing and scaling spray drying processes for pharmaceutical applications requires deep process understanding, validated infrastructure, and absolute regulatory confidence. At Glatt, we support you from the very first idea through successful scale-up and into routine production.

In our Glatt Innovation Center, our experts carry out spray drying trials to evaluate feasibility, optimize process parameters, and support early formulation development. These trials provide a solid technical foundation for robust, scalable spray drying processes.

Beyond feasibility testing, Glatt's Pharmaceutical Services offer formulation development, spray drying trials, and small-scale production under GMP-compliant conditions, meeting the requirements of FDA, EMEA and international regulatory authorities. This enables you to generate representative process and product data early in development – safely, reliably, and in full compliance.

From Pharma FAT to Pharma SAT and beyond

Our on-site service does not stop at process development. Glatt accompanies you throughout the entire lifecycle of your spray drying system.

From Pharma FAT (Factory Acceptance Test) at our manufacturing site to Pharma SAT (Site Acceptance Test) and start-up at your own facility, we provide structured hands-on support.

Our on-site services cover:

- → Installation and commissioning
- → Qualification and validation support
- → Performance optimization under real production conditions

During routine operation, our global service network ensures your systems continue to perform at peak level. If issues arise, our experts carry out structured diagnostics, replace critical components using certified OEM spare parts, and validate the restored performance together with your team.

GLOBAL SERVICE. LOCAL PRESENCE.

Our fast and expert support is available whenever and wherever you need it – remotely, directly, and on site.

Our global service organization with strong local presence provides immediate assistance in case of technical issues, minimizing unplanned downtime and ensuring stable production.

VISIT US!
glatt.com

Integrated Process Solutions.