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Choosing a Spray Drying Manufacturer: Why Flexibility and Customizability Matter

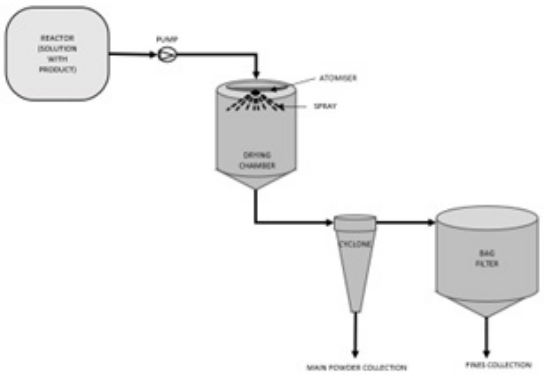
By **Ana Vilão**, Spray Drying Manager, *Esteve Quimica*

The spray drying of active pharmaceutical ingredients (APIs) is a technology widely used to enhance bioavailability for poorly soluble materials, dry heat-sensitive pharmaceuticals, and perform particle engineering. Spray drying is a process in which a solution of API and a polymer are rapidly dried to produce an amorphous powder. The fact that it allows for the customization of powder characteristics, particularly solubility, renders it a preferential technology for the increasing number of molecules that have become pharmaceutical candidates in recent years.

Spray Drying Process

Spray drying is a continuous drying process in which a prepared liquid solution is dried into an amorphous solid powder. It involves the atomization of the liquid into very small droplets (spray plume) using a spray atomizer or nozzle. There are several types of atomizers that can be used (two-fluid, pressure, ultrasonic, or rotary) depending on the process. In the pharmaceutical industry, the most common ones are two-fluid nozzle and pressure nozzle. The atomization process occurs inside the drying chamber, where the small droplets interact directly with a current of hot drying gas that will evaporate the solvent and allow the formation of the particle. There are a few variations to the setup of the drying gas. It can be co-current or counter-current. The systems can also have recirculation or not, known as closed- and open-loop systems, respectively. The spray dryers most commonly used in the drying of active pharmaceutical ingredients operate in co-current and closed loop for process optimization purposes. Both aqueous and organic solvent systems can be used in the process of spray drying pharmaceutical powders, and different types of drying gas can be utilized, such as air, nitrogen, or argon.

The formation of the particle occurs by performing flash drying inside the drying chamber, after which the particles are then separated from the gas stream using a cyclone and/or bag filter. Cyclones are the preferred option used in the pharmaceutical spray drying processes because they can be designed for high recovery efficiency and consist of a simple mechanism with no moving parts where the gas stream containing the particles is fed tangentially into the top of the cyclone. A vortex is created inside the cyclone and the product will fall into the bottom of the equipment where it is collected.



Spray Drying process

Spray drying is one of the technologies used for particle engineering in the pharmaceutical industry. By engineering or designing the particles, the final powder attributes can be manipulated and controlled. The spray drying process allows the control of properties such as the particle morphology, the particle size, the powder density, and the level of moisture or residual solvent in the powder. These characteristics can be engineered to a great extent to achieve a downstream process' required targets. Spray drying typically produces amorphous, near-spherical particles with favorable flow characteristics.

Spray Drying at Esteve Química

Improving the efficiency and reliability of processes in the face of tight timelines is one of Esteve Química's core specialties. It operates as a boutique contract manufacturing organization (CMO), offering customers the flexibility to dictate their individual needs within Esteve Química's quality and service framework.

Esteve Química also works to be flexible in the face of process challenges, so that an issue in the project does not automatically translate to a delay in manufacturing. For more than a decade, Esteve Química has established a core team for each of its projects, designed to maintain constant contact between the customer and Esteve Química´s counterparts. These core teams, led by a project manager, and involving experts in quality control, R&D, production, procurement, EHS, and quality assurance, manage the project technical aspects and maintain fluent communication with one another and with their counterparts for the life of a project.

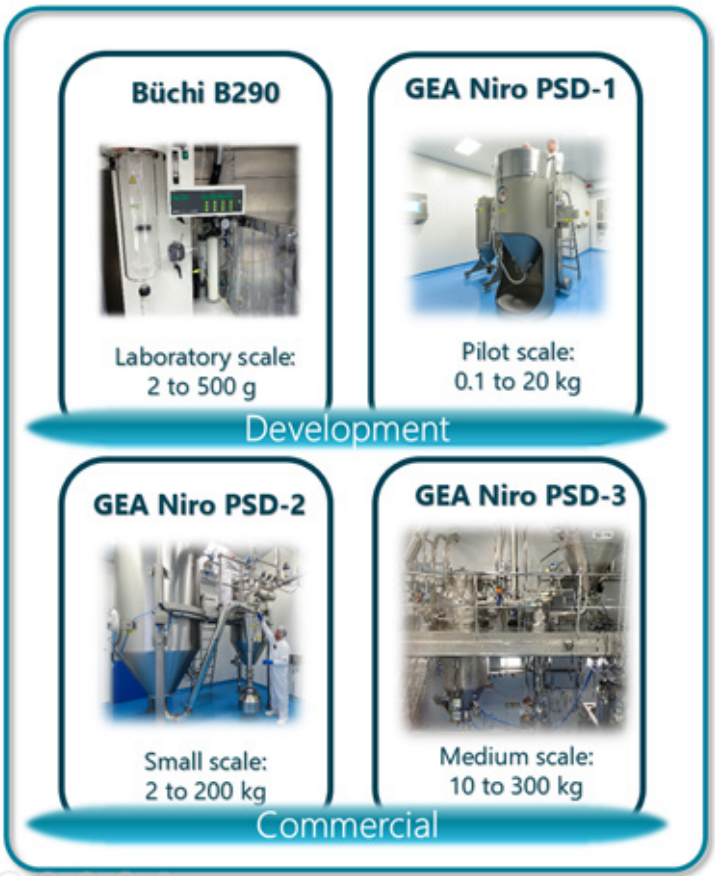
Choosing the right CMO for a process requires a comprehensive evaluation of a potential partner's strengths – from an organization's capabilities to its track record to its facilities and expertise. Finding the right partner can be a complex endeavor. This is particularly true for companies pursuing therapeutics with complex chemistries or spray drying needs. Finding a CMO with both the experience and flexibility to enable tight turnarounds, drive continuous optimization, and promote safety and efficacy is essential to safeguarding scale-up for these therapies.

Spray drying for pharmaceutical intermediates is one of the company's well-established areas of expertise. Esteve Química has significant experience in spray drying and its quality systems and processes have been approved by regulatory bodies around the world, including the U.S. FDA and regional agencies. Our average timeline for a spray drying application from tech transfer to completing an evaluation campaign is six months, and our experienced team can offer flexible and tailored solutions to support spray drying process requirements.

Equipment and Capabilities

Located inside the perimeter of the manufacturing site at Celrà (Spain), the spray drying plant is positioning itself as a strong CMO to serve companies worldwide. Equipped with state-of-the-art cGMP facilities and solid form characterization laboratories, Esteve Química offers integrated R&D, analytical, and manufacturing services that can support a process from early-stage development to scale-up and technology transfer.

Esteve Química's skilled team of scientists and engineers works in collaboration with the customer to address their needs. Solvent and polymer screening, quality by design development, particle engineering, and process optimization are some of its most highly demanded services.



Esteve Química's spray drying capability

Finding a Flexible and Bespoke Spray Drying Manufacturer

Any pharmaceutical company contemplating an outsourcing strategy means they are considering entrusting an external organization with the manufacturing of their product. Pharmaceuticals undergo years of development and significant investment, which weighs heavily on organizations when choosing an external supplier. Therefore, this decision necessitates a concerted approach to carefully vetting potential partners.

Finding a CMO willing to work closely with its clients to understand their processes, products, and goals is critical to commercial success. Equally important is a CMO's flexibility in the face of emergent issues – are they able to adapt to potential setbacks? Will they prioritize a project's success in the face of competing priorities? Evaluating a CMO on the basis of its intangibles, including its attitudes regarding work ethics, timelines, and expectations, can matter just as much, or more, than its equipment or facilities.

At Esteve Química, this commitment to ensuring client success permeates every segment of its business. This commitment is reflected in the way it tailors its approach to individual projects. Where many larger or midsize CMOs have worked to cultivate a one-size-fits-most approach that serves to cover their bases and apply broadly across their project portfolios, Esteve Química works to incorporate a client's own workflows into its approach. It's a strategy that works for all types of pharma companies; whether you are a big pharma, midsize biotech, or even a smaller startup, you can expect a one-to-one alignment between members of your own team and the team at Esteve Química.

With a robust supply chain and a wealth of technical expertise, Esteve Química can offer customers unmatched reliability and flexibility across a range of disease indications and therapeutic modalities. With its collaborative approach to project management, coupled with a proven track record of quickly and seamlessly transferring and scaling processes, Esteve Química possesses both the personnel and resources to help partners achieve lasting commercial success. To learn more about spray drying, click here, or visit esteve.com.

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About the Author

Ana Vilão holds a degree in Chemical Engineering from Instituto Superior Técnico (Portugal) and is a Chartered Engineer (MIChemE). She has more than 15 years of industry experience at Esteve Quimica, Thermo Fisher Scientific, GSK, Pfizer and Hovione. She is the Spray Drying Manager of Esteve Quimica and in this position, she is responsible for the Drug Product Intermediate (DPI) Pharmaceutical Operations, which includes a state-of-the-art Spray Drying Plant. She leads a team of operators, engineers and scientists that are responsible for the development, scale up and manufacturing of DPI processes. She joined Esteve Química in 2020 as an Industrial Process Lead and in the following year she took on board the management of the Spray Drying Department.