

Bürkert delivers gas control system for aseptic spray dryer

08 August 2023

Spray drying technology offers the pharmaceutical industry a continuous process to convert a liquid active pharmaceutical ingredient (API) into a powder, as an alternative to freeze drying. The process has been used in other manufacturing processes for several years and is gaining traction in the pharmaceutical industry. In 2015, Nova Laboratories Ltd received FDA and EMA approval for the aseptic manufacture of a spray dried pharmaceutical product. The company has worked with Bürkert to develop more of its own spray drying equipment, which will be used to support customers in delivering powdered products aseptically.

Nova Laboratories offers a wide range of manufacturing processes and products to the pharmaceutical industry, developing its own in-house processes that are regulated and approved by industry bodies. The development of its latest aseptic spray drying process has involved the company's own designers as well as specialist suppliers such as Bürkert.

Meeting aseptic specifications

Aseptic spray drying offers several advantages for biopharmaceuticals manufacture. These include particle engineering capability to enable unique final presentations, enhanced bioavailability of poorly soluble compounds as well as long-term thermal stability. As an aseptic process, it is also suitable for products that

cannot be terminally sterilised. Already experts from pioneering aseptic spray drying, Nova Laboratories recognised the need for a new, intermediate sized spray dryer within its portfolio. Suitable for early phase clinical work, Nova Laboratories appreciated the advantages this new spray dryer could offer its customers by providing a pathway from development work at Nova Laboratories through to clinical trials.

The spray drying process involves very small droplets of the feed liquid meeting a hot drying gas and flash drying it into small particles, which are then separated from the gas by a cyclone. A robust control system is required to control the process parameters to achieve the critical quality attributes of the product.

The equipment is designed and constructed to comply to cGMP requirements, not least EN 10204 3.1, which broadly covers all the materials used to create the process equipment. Sam Green, Equipment Projects Manager for Nova Laboratories, explains: “We have considerable in-house design capabilities, but for this project, it was clear we needed to engage some additional expertise. With the control of the drying gas such an important aspect of the process, we turned to Bürkert for additional support.”

From concept to delivery

For projects such as this, Bürkert has teams of experts that can develop a design, deliver a proof of concept and manufacture the full-scale process control system. In this case, the whole design was created by the Systemhaus team in Menden, which was assigned the project and saw it through from concept to delivery of the final process control system. Using Bürkert’s own products to ensure optimum compatibility and precision, the team in Menden worked closely with the

development scientists and design engineers at Nova Laboratories to deliver their concept.

Due to the varied nature of the liquids and emulsions that would form the feedstock for the spray dryer, process control and adjustment were very important. Droplet size, gas flow rates and heating characteristics needed to be very carefully controlled as well as being fully documented for each batch. Due to the very high value of the feedstock, there is no opportunity to complete trials; the process must deliver the perfect product first time. Nova Laboratories used an industry-leading supplier for high level control, and batch documentation, and Bürkert for the pneumatic control.

Sam continues: “We already had a very positive experience with Bürkert equipment and how it complemented our existing process control systems. We knew that we could hand over a list of our requirements and Bürkert would be able to deliver a turnkey solution that would enable us to provide a new spray drying service for our customers.”

Precision gas control

One of the most crucial characteristics to control in spray drying is the flow rate of gas. It is used to atomise the feedstock, to carry the droplets/powder in the drying chamber and is used for secondary drying processes. In all three applications, the gas is controlled by a Type 8746 mass flow controller, while the nozzle gas is monitored by a Type 8742 mass flow monitor to ensure the correct nozzle pressure to deliver a droplet size between 30 and 120 microns.

Each line can be isolated using electromotive valves and pressure sensors are also installed on the supply line as well as the four output lines. The whole system is fully automated and 3.1 material certification was provided for all components.

Sam explains: “The way in which all the people involved in this project collaborated was excellent. The fact that Bürkert was able to provide 3D CAD drawings of all the components really helped us ensure the whole process control system was going to fit the limited footprint. This is very important in modern pharmaceutical applications and together with their expertise in gas flow metering, we have achieved a very successful outcome.”

Process validation

Bürkert engineers were onsite for the commissioning, working with other contractors involved in the project to ensure the new process was delivered on time. Validation has been completed and process yields were exactly as expected, ensuring that the new equipment is ready to receive products from customers.

Dr James White, Deputy Managing Director and Head of Engineering at Nova Laboratories concludes: “Our development of this new aseptic spray dryer will enable us to support a wider range of customers with a pathway from development work to early phase clinical work for pharmaceutical powders. This new equipment has certainly benefitted from Bürkert’s expertise, ensuring we have a flexible and fully qualified process that can expand our business.”

Image captions:

Image 1: Nova Laboratories development of its latest aseptic spray drying process has involved the company's own designers as well as specialist suppliers such as Bürkert.



Image 2: In all three applications, the gas is controlled by a Type 8746 mass flow controller, while the nozzle gas is monitored by a Type 8742 mass flow monitor to ensure the correct nozzle pressure to deliver a droplet size between 30 and 120 microns.

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About Bürkert

Bürkert Fluid Control Systems is one of the leading manufacturers of control and measuring systems for fluids and gases. The products have a wide variety of applications and are used by breweries and laboratories as well as in medical engineering and space technology. The company employs over 2,200 people and has a comprehensive network of branches in 35 countries world-wide.

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