

From laboratory to process

Modular mills adapted without specification sheets

When planning complex systems these days, it's difficult to imagine not having a specification sheet, and mills for pharmaceutical production – which must guarantee a high OEB level and Atex conformity at the same time – are no exception. However, Frewitt's experience with a pharmaceutical contractor from the United Kingdom demonstrates that under certain circumstances, it can also work without.

The project manager at a contract manufacturer, accompanied by the end user, was seeking a new milling and powder-handling solution and requested a meeting with Frewitt at the Interphex NYC trade fair. At the time, neither the project manager nor his company had any experience with the milling specialist from Fribourg, Switzerland, but had previously been working for many years with competitors' mills. When the production areas were reorganised with the aim of enabling heterogeneous solids, notably active pharmaceutical ingredients (API), to be processed using a single multi-purpose system, they decided to look around for a proven innovator active in this sector.

In the course of the conversation it was quickly agreed that a milling test on the site of the contract manufacturing organisation (CMO) would be essential to arrive at a final decision. No sooner said than done: as a first step, two Frewitt machines were shipped to the customer's plant in the UK. One was a Fredrive-Lab laboratory mill with a hammer milling head and a conical grinding head and the other a Fredrive system designed for production quantities with a Hammerwitt-3-type grinding head plus an interchangeable Coniwitt-200-type grinding head.

The results of the product tests provided clarity. The successful and significantly better outcomes of test series with all variants quickly persuaded the contractor to purchase the Hammerwitt-3, which was already under rental at the end user. This decision also paved the way for the future, large-scale production system, which Fre-



Pictures: Frewitt

Complete plant for processing heterogeneous solids: a discharge aid feeds the ground material from the storage vessel into the hammer mill and dosing unit (on the left in the picture). The material is then filled into an endless liner (right) in a combination of a storage vessel with a discharge aid and a Profi Dos dosing unit with a Profi-Clean ventilation system.

witt was tasked with supplying as a turnkey solution. The ease of changing the milling head and product as well as the general cleanability and handling of the mills were key arguments here.

Modular plant concept

Since the contractor did not know in advance whether they would be required to process a hard, crystalline, soft, fibrous, toxic or even potentially explosive product, the system had to be given a modular design and seamless product changes enabled. After multiple rounds of discussion, the processes were defined, providing a basis for drafting the system concept and the submission of an offer to the customer. The system was initially equipped with a hammer mill with a conical and a cylindrical grinding head (sifter), to allow products with various material characteristics to be pulverised, disagglomerated, homogenised, ground and fine-ground. The Atex directive was observed to ensure a safe process whenever the customer needs to mill potentially explosive products.

All processes monitored

As always, a rigid inspection of the process parameters is necessary for API production on account of the high occupational exposure band level and the Atex zone classification. Hardly any element or part of the system exists which isn't controlled and monitored by probes, sensors or sensing devices. For example, fill level sensors prevent product clogging, oxygen sensors measure the oxygen content, pressure sensors monitor the nitrogen pressure and temperature sensors determine the temperature at sensitive points on the machine, protecting both the process and the products. The two buffer tanks alone – one located at the inlet and the other in the middle part of the system – are equipped with a total of eight sensors to be able to measure products levels, pressures and oxygen content. In addition, the two 500 l tanks each have a viewing

window to permit visual inspections. When processing potentially explosive products, a monitoring system constantly measures the oxygen content at the Profi-Clean dust removal system's outlet. Two measuring sensors are installed here to be on the safe side. The arrangement of the sensors at this location ensures that the entire system is filled with nitrogen and that the grinding process begins only after sufficiently low oxygen levels are detected at the Profi-Clean outlet.

Oxygen content under control

When processing potentially explosive substances ($E_a \leq 1 \text{ MJ}$), the product is fed into the first buffer tank until the specified quantity is reached. The valve at the container inlet closes and the buffer tank is rendered inert while the oxygen content is monitored. The same thing happens with all other parts of the system. As soon as the oxygen content reaches 3 % throughout, the dosing system and the mill start up. Production can then begin in the closed system. If the oxygen content rises, nitrogen is automatically injected until the oxygen falls below the critical level again. However, if the prescribed maximum oxygen content of 5 % is exceeded, the machine stops immediately. Due to the constant monitoring of the system, oxygen – as a critical risk factor – is always under control and the system is therefore protected against explosion.

Integrated insulators

Three large insulators, arranged over three levels, are combined with the Frewitt milling system. The first insulator is installed at the inlet of the buffer tank, the second in the area around the milling head and the third close to the dosing, weighing and filling system at the system outlet. The operator can enter parameters, set and query values, evaluate alarms and perform many other process-relevant functions on a central HMI. What began with a question and an idea developed at a trade show in the USA



Hammerwitt-6 hammer mill with dosing unit

ultimately led to the installation of a high-tech system, which today manufactures products with very different characteristics according to the highest standards.

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AUTHOR
MATTHIAS HONISCH
Regional Sales Manager,
Frewitt