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BOHLE INNOVATIV

WE DEVELOP YOUR FUTURE.

The Bohle-Conti-Granulator BCG 30:

The core of continuous production

In the last issue of Bohle Innovativ, No. 2-2007, we discussed the advantages of a continuous production process. Today, we focus on the core of the continuous production process: the granulator with integrated dryer (Bohle-Conti-Granulator BCG). The 30 means the capacity per hour in kilograms. The innovative Bohle concept for continuous granulation is based upon the following design principles:
The integration of the granulator together with the dryer permits the use of a harmonized control system. The curved bottom of the Bohle Single-Pot-System is well tested and proven for

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In this issue:

Dear readers, **March 2008**

in 2007 our company faced two main facts: First, in the first half of the year, some customers delayed their investment decisions. However, in the second half, our customers proved their trust in Bohle with a significant number of orders. We are sincerely grateful for the orders received and will honor these with our excellent quality products and on-schedule deliveries, without exception.

Second, our current coating technology has proven to be enormously successful in the market. The main advantages of Bohle's technology are a considerable reduction of spray drying and an extremely high coating uniformity. Also warranting mention are the fast and efficient spraying and cleaning times. Both are drastically reduced when compared to other technologies within the market. This combination of attributes and Bohle's standard of excellence were compelling to our customers in placing their orders.

We send you this issue of our client magazine in preparation of the most important exhibition in 2008, **Interpack** in Düsseldorf, Germany. Since our founding year in 1981 we have had a presence at Interpack, showing our innovative new products. This year is especially important as we will present an innovation which will surely have a profound impact in the world of solid dosage production: the Bohle-Conti-Granulator BCG – continuous granulation with integrated drying. Promising test results to date point to a wonderful milestone for the pharmaceutical industry. No comparable product currently exists in the marketplace, and several patented advantageous concepts of the BCG make continuous production of wet granulates possible. Solids and binding liquids are added continuously, extraction and drying likewise occur continuously. Drying within the contact dryer offers obvious benefits:

The rotation of the heated stainless steel drum ensures continuous drying from all sides thereby eliminating wet "nests"; and the drum has a vacuum of 50-60 mbar which keeps drying temperatures less than or equal to 40°C.

Furthermore, the BCG is yet another element within our product line suited for high containment applications. Via integration of Bohle's BCK high containment valve, granulate can be produced in the BCG and discharged, totally contained, to a conveying system or a receiving container. The BCG therefore satisfies all requirements for pharmaceutical solid dosage production.

We cordially invite you visit our Bohle stand, G28/G36 in Hall 3, at Interpack 2008 in Düsseldorf. We look forward to discussing our exciting new offerings and sharing some refreshments.

Best wishes from Ennigerloh
Your

➔ Continuation Conti-Granulator

formation of granulate. Above the impeller, an integrated horizontal outlet in the process bowl enables continuous granulated discharge.

A chopper mounted above the impeller carries granulate through a sieve thus achieving a defined granulate size.

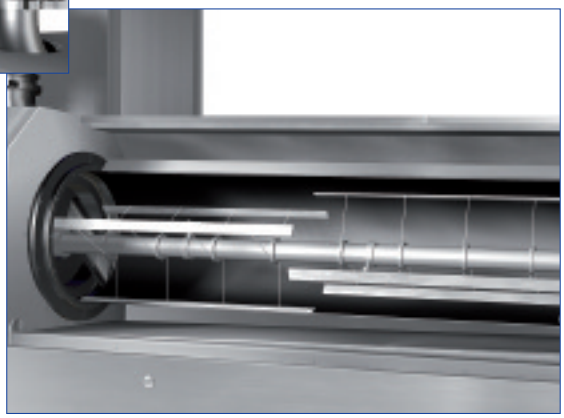
To avoid unnecessary product adherence to the bowl surface, product contact surfaces are minimized and simplified. Critical surfaces are cleaned by scrapers in order to avoid mixing of old and new material. During the drying process, low gas flow is utilized to avoid in-process filter changes and to reduce the number of start and stop phases.

The drying unit incorporates a heated rotating tube under vacuum to guarantee quick and gentle product drying.

The BCG is designed for high containment applications. Contained integration to other equipment is readily attained through the use of Bohle's BCK high containment valve. ■

Granulator of the BCG 30

Dryer of the BCG 30



The Bohle-Fluid-Bed System BFS 30: The new look of Granulation

The new generation of fluid bed systems offers many exciting, new concepts. The Bohle BFS is suitable for drying, granulation, layering and pellet/particle coating without any optional modifications. This new processing design is much more robust than traditional Wurster technology.

Due to the shift from top-spray technology to tangential-spray technology, the latest design of the BFS is extremely compact and reduced in overall height. Furthermore, a self-supporting structure without additional side bearings is incorporated to enable simple access and exterior cleaning. Spray nozzles are arranged tangential to the product bed and can be exchanged during the process from the outside. The BFS includes large sight glass ports without intrusive fasteners for easy cleaning and unobstructed product visibility. The product bowl is equipped with an integrated bottom discharge valve. Using vacuum transfer, raw materials can be introduced into the bowl through the discharge valve. The standard BFS comes with a hinged process bowl which can be swiveled sideways, eliminating the need to disconnect media supply lines before opening the system.

This feature permits effortless interior access for maintenance and inspection procedures. The bowl's bottom plate is conical for improved flow and increased rigidity. This special conical design eliminates unsightly structural ribbings. Additionally, the bottom plate is attached and removed via a single point for ease of handling. The established and accepted Bohle filter technology has been further improved with new air filter handling, cleaning and storage features. Single filter elements can be cleaned much more effectively with these improvements. The filter unit is moved with a new and efficient compact drive system. Thanks to this new drive unit, the BFS now utilizes a cleaning element in the center of the process pivot pin to guarantee optimum product filter cleaning. The new BFS 30 is currently available in our Service Center in Ennigerloh, Germany, and can be reserved for your individual trials. ■

News in Coating Technology:

The Bohle-Film-Coater BFC 5 with Isolator

To face the challenge of ever-increasing safety requirements and operator protection from active pharmaceutical ingredients, L.B. Bohle has designed the Bohle BFC 5 laboratory coater for contained coating applications. The BFC 5 coater's versatile design allows for simple integration of isolator technology (glove box) thereby ensuring operator safety during the handling of toxic/potent substances. For applications where the product is not hazardous, the BFC 5 can be used without an isolator.

The BFC 5 includes two different sized coating pans (for either 5 or 10 kg batches) which are easily interchanged. With the optional divider plate installed, batches as small as 500 grams are possible. The BFC 5 laboratory coater provides secure scale up results to all larger L.B. Bohle machines like the Bohle-Film-Coater BFC or the Bohle-Tablet-Coater BTC. The BFC 5 is a mobile coating unit that contains all technical modules, such as the complete air handling system and electrical cabinet, in its housing. Using a patented, through-the-tablet-bed air flow design within the coater, the BFC 5 significantly minimizes spray drying and the loss of coating suspension resulting in a highly efficient and effective coating process. The geometry of the coating pan and the integrated double-helix mixing spirals lead to superior mixing of the cores with the gentlest handling possible. →

➔ Continuation BFC 5

The design allows for a fully automated discharge cycle, resulting in no tablets left in the pan. The spray arm containing the spray nozzle assembly is mounted to the front door. By opening this door, the two nozzles are easily accessible for inspection or maintenance (see picture above). The spray gun angle and bed distance can be adjusted without opening the front door of the coater. A completely welded housing minimizes edges and corners to ensure easy cleanability. The isolator (glove box), supported by a frame with castors, is easily implemented into the BFC 5. The isolator is equipped with four (4) gloves, made of FDA-approved materials, for ergonomic handling within the chamber. A rapid transfer port (RTP) is incorporated on the isolator to facilitate contained material transfer to and from the isolator and coater. Adjustments to the coater (nozzles, sampling, and all other manual actions during coating) can be done via the isolator. An internal spray gun is provided in the isolator for cleaning/rinsing of the isolator inner surfaces. In conjunction with the internal isolator spray device, the BFC 5 can be equipped with a simple washing system to wet all surfaces inside the pan and pan housing. After washing the coater and isolator, the isolator can be simply disconnected and removed for further cleaning of both devices if required. ■

The Bohle-Film-Coater BFC:

Coating Uniformity Technology Leap

The Bohle-Film-Coater BFC is an alternative to the usual pan coater. With an innovative process concept, the coater is characterized by its superior functionality and excellent results.

Obvious process technology advantages can be seen in the Bohle air handling philosophy within the coating pan. Spray drying is virtually eliminated, reducing spray solution losses and improving the structure of the tablet coat. Tablets are handled gently thanks to the pan geometry and the unique blending elements.

Even with such technological benefits, the Bohle BFC film coater is still classified as a perforated pan coater according to SUPAC guidelines. This classification acceptance is invaluable for new capital equipment appropriation and process validation efforts.

The unique blending baffles result in outstanding blend uniformity at slower speeds and in shorter times. This is the pre-condition for good coating uniformity as well. The coating uniformity of the Bohle coater has been tested multiple times from laboratory scale up to large production scale (batch sizes from 4 to 850 kgs) all with similar results. Coating uniformity measured as relative standard deviation in weight gain (RSD) of the coating film only are in a range from 2.5% to 4.5%. For active coating or functional coating like enteric coating this is essential to fulfill easily the demands of the Pharmacopeia (USP or Ph.Eur.). These superb results can even be beneficial for simple cosmetic coats or taste masking where the total amount of coating fluid can be significantly reduced, lowering the overall process cost when compared to a regular pan coating process. ■

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