Complete systems for recipe development

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With its tailor-made turnkey technological solutions based around the ZSK twin screw extruder, Coperion is responding to the growing demand from the pharmaceutical industry for systems for continuous production processes that offer higher efficiency and uniformity than batch processes. One example of this is a complete pharmaceutical system with a ZSK 18 MEGAlab twin screw extruder with an 18 mm screw diameter that was recently delivered to an international pharmaceutical company. This fully integrated system includes two Coperion K-Tron gravimetric loss-in-weight feeders with superior accuracy in API and liquid feeding, a cooling belt, and a Coperion Pelletizing Technology strand pelletizer. With a maximum throughput rate of 10 kg/h, it is suitable for both wet extrusion and continuous hot-melt extrusion (HME) on a laboratory scale. In the implementation of this system, Coperion leveraged its experience that spans over 30 years in specialty applications for recipe development as well as large production systems for this demanding industry. April 17-19, 2018 Coperion presents its technological solutions at Interphex 2018 (New York, NY, USA, Booth 2261).

Precise, reproducible product quality

One reason for the continually increasing importance of HME processing in the pharmaceutical industry is its intensive mixing effect, as offered by Coperion's co-rotating ZSK twin screw extruders. As a result, active substances and excipients can be dispersed very finely and homogeneously in pharmaceutical polymers without the use of solvents, which promotes a high degree of bioavailability of the APIs (also BCS classes 2 & 4). In addition, the self-wiping screw profile of these systems eliminates dead spaces. Due to the specific torque of 11.3 Nm/cm3 which allows low ratios of throughput to screw speed, the thermal stress on the APIs and polymers in the ZSK process section is low. Combined with the customized peripheral equipment, these systems make it possible to precisely adhere to the recipe and to create a reproducibly high product quality. In addition, process steps, such as encapsulation or taste masking, can be integrated into the process.

Highly accurate and customized feeding of the ingredients

The integration of the Coperion K-Tron feeders for complete systems ensures optimal dispensing of the formulation ingredients. Coperion K-Tron is known for its highly accurate feeding solutions for pharmaceutical applications. The feeders, which are available as volumetric or gravimetric models, demonstrate a high level of reliability, especially in continuous processes. The wide range of feeder designs makes it possible to feed a very wide range of materials from the finest powders and pellets to liquids and pastes to a pharmaceutical process very precisely. Suitable feed systems are even available for ingredients with demanding properties, such as poorly flowing or sticky materials, flooding powders, temperature-sensitive liquids, or substances with a high hazard potential. For complex recipes, several feeders can be grouped around an extruder inlet.
At this year's Interphex, Coperion K-Tron is pleased to display the newest innovation in pharmaceutical feeder design. The new feeder and scale combination includes modularity for quick feeder exchange, easier access and cleanability, as well as a smaller footprint, ideal for multi feeder clustering around continuous processes.
All Coperion K-Tron feeders have always been specifically designed to meet the stringent requirements of this industry, including compliance with GMP guidelines and the use of FDA-approved construction materials.

Modular system provides maximum flexibility

All ZSK pharmaceutical extruders have a compact design, are easy to operate, and offer optimal accessibility for cleaning and maintenance. For maximum flexibility when feeding liquids and devolatilizing the melt, Coperion uses a modular design for the process section, which includes several barrels in which the co-rotating screws operate. The size-independent Do/Di ratio (outer screw diameter to inner screw diameter) of 1.55 allows reliable scale-up. The systems are designed to comply with GMP guidelines. Customers receive complete documentation for all process parameters (V-Lifecycle) based on a URS (User Requirement Specification).

Precise pelletizing solutions

Coperion Pelletizing Technology offers suitable pelletizers that are specifically designed for pharmaceutical applications. The systems are characterized by their high level of reliability and product quality and have proven themselves many times in practice. Appropriate materials and surfaces are used in order to meet the high requirements of the pharmaceutical industry. Special attention is paid to making the systems easy to access and to clean. Other features, such as pellet length adjustment, can also be realized.
Stefan Gebhardt, General Manager of Business Unit Food & Pharma at Coperion, says: "Like all industries, the pharmaceutical industry is constantly striving to increase process efficiency. Our continuously operating ZSK extrusion systems offer interesting potential, as they increase productivity in comparison to conventional batch processes without compromising on quality, and they require less space. The FDA also supports the trend towards continuous processes because they can accelerate product development and reduce production time. And, as the last link in the chain, patients also benefit from the use of our extruders because the intensive dispersing effect can increase the bioavailability of the incorporated pharmaceuticals, and therefore optimize the effect."