

Pharmaceutical ingredient feeding often creates several questions, due to the strict requirements for specific product handling, process engineering and design. This sheet will address some of those important questions.

WHAT IS BEST FEEDER CONFIGURATION FOR DIFFICULT FLOWING PHARMACEUTICAL POWDERS?

Due to the cohesive nature of most excipients and API's, the twin screw configuration is best suited. The self-wiping effect of the twin screws avoids the buildup issues and inconsistent flow typical when using single screw designs. For extremely difficult powders which might have a tendency to bridge or rathole, Coperion K-Tron can also provide the innovative ActiFlow Bulk Solids Activator device to ensure consistent screw fill and optimal accuracy. In addition, for cases where the feeders may be susceptible to back pressures or vacuum from the processes below, our newest technical innovation is available: Electronic Pressure Compensation (EPC). This package is ideal when feeding into continuous or semi-continuous processes such as mixers, mills/micronizers or extruders, for optimal accuracy in feeding.

WHAT ARE ADVANTAGES OF HIGH ACCURACY FEEDING FOR CONTINUOUS PROCESSES?

Most continuous processes – whether mixing, granulation, or extrusion – are usually “slaves” to the feeders. In other words the feeders set the flow rate. The more accurate the mass flow of ingredients is from each feeder, the more consistent the output of the conversion step will be. This is especially important at low feed rates, where many outside influences can affect feeder accuracy. Therefore a highly reactive controller, mechanical design and load cell combination – as found in Coperion K-Tron pharmaceutical feeders – is critical.

CAN THE FEEDER BE DESIGNED TO FEED HIGH POTENCY ACTIVE PHARMACEUTICAL INGREDIENTS?

Coperion K-Tron pharmaceutical feeders can be easily integrated into gloveboxes, or fitted with split butterfly valves to ensure total containment. The specialized sealed design is equipped with inward purges and special sealing. When integrated with Coperion K-Tron P-Series vacuum loaders and receivers for automatic refill during continuous operations, a completely sealed design can be provided.



WHAT IS THE ACCURACY PERFORMANCE?

Coperion K-Tron loss-in-weight feeders have been designed to perform to the following standards:

Repeatability: $\pm 0.25\%$ to 0.5% of sample average

Linearity: $\pm 0.25\%$ of set rate

The diversity of materials and their associated handling characteristics require that linearity performance for a particular combination of feeder and material be determined through laboratory testing.

IS VALIDATION DOCUMENTATION AVAILABLE?

Yes, Coperion K-Tron offers a variety of validation options including FDS, FAT and SAT IQ/OQ.

HOW EASY IS THE PHARMACEUTICAL FEEDER TO CLEAN?

The Coperion K-Tron Pharmaceutical feeder is designed for easy assembly/disassembly through the use of quick release clamps and easy access sealing. The unit can be designed for wash in place using integrated retractable spray ball assemblies. Special SIP options are also available for single screw models. Further detail on the ease in disassembly can be seen in the pharmaceutical feeder video on our website or our youtube channel.

CAN WE DO TRIALS IN A LAB?

Feeder trials for both batch and continuous feeding are often useful to determine the optimal equipment configuration for a particular application, especially for difficult materials. Coperion K-Tron has fully equipped test labs at each of our plants in

the USA (Pitman, NJ and Salina, KS), Switzerland (Niederlenz) and China (Shanghai). Smaller test lab facilities are available at other locations. Services include the following:

- Feeder trials including auto-refill
- Vacuum sequencing dilute phase conveying
- Continuous vacuum & pressure dilute phase conveying
- Vacuum & pressure dense phase conveying
- Bench tests

WHAT ARE THE MATERIALS OF CONSTRUCTION FOR PHARMACEUTICAL EQUIPMENT?

All product contact parts on pharmaceutical feeders and loaders/receivers are AISI 316L with FDA approved seals and elastomers. All standard surface finishes are 0.8 micron Ra with options for 0.4 micron Ra on product contact surfaces. All construction is done to cGMP design standards. As stated above, specialty designs for containment and WIP (wash-in-place) are also available.

To download other papers in this series, or for more information on Coperion K-Tron equipment and services, please visit

www.coperion.com