

Background

Coated tablets are defined as tablets covered with one or more layers of various substances such as resins, gums, inactive and insoluble fillers, sugars, plasticizers, waxes, authorized coloring materials, and sometimes flavors. Tablet coating processes can be subdivided into different types. Sugar coating, for example provides a combination of insulation, taste masking, smoothing of the tablet core, coloring and modified release. Film coating, on the other hand, is usually a single stage process and easily adaptable for controlled release dosage forms.

Substances used for coating processes are usually applied as a solution or suspension under conditions where the carrier substance evaporates. In the case of sugar coated tablets, either via batch or continuous processing, the tablet must be polished to achieve a final aesthetic quality. Polishing is achieved by applying a mixture of powder waxes, such as carnauba wax, to the tablet in the polishing pan.

Conversely, in the case of film coated tablets, the addition of

powdered opaquant extenders, such as talc, achieves a lighter color and greater film coverage.

In both of these coating processes, Coperion K-Tron twin screw feeders are used to provide consistent and metered delivery of these dry powders, directly into the coating equipment.

Application and Process Details

In order to efficiently deliver the powdered materials to the coating process, a Coperion K-Tron pharma feeder complete with a gas venturi on the feeder outlet is provided. The powdered materials (such as carnauba wax as illustrated in the process diagram below) are fed continuously by means of a twin screw feeder directly into the gas injector. Twin screws are used due to their suitability to accurately meter cohesive materials, without material buildup in the screw trough. The gas in the venturi line conveys the powder to nozzles which are affixed inside the coating equipment. The nozzles are mounted in such a way that a consistent and even flow of the powder is delivered throughout the coater, thus en-



Volumetric pharmaceutical feeder with gas venturi on outlet

suring the required polishing or increased film coverage effects.

Typical features

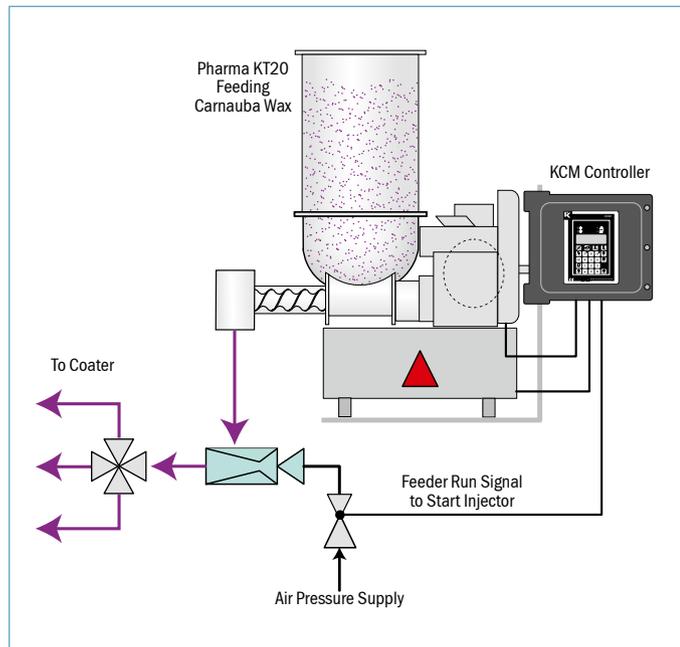
- Gravimetric or volumetric feeder configurations. NOTE: As indicated on page 2, use of the gravimetric design allows for validation of the exact powder quantity delivered and ensures higher accuracy.
- K-PH-KT20 pharmaceutical feeder design, complete with sanitary construction, for

typical powder flow rates of 1.5 to 60 kg/hr (3.3 to 132 lb/hr).

- Optional integrated screen design in screw outlet to ensure consistent and even powder flow to the venturi, and deter product lumps or aggregates.
- Venturi injector controls include pressure regulators and integral interlocked pressure switch to ensure flow of conveying gas to the venturi device.
- The use of the venturi at the feeder outlet eliminates the need for traditional powder delivery methods direct to the coating drum utilizing extended screws.



Feeder outlet with venturi injector



Volumetric vs. Gravimetric Feeding

As shown in the graphics below, the twin screw feeder can be supplied in either a volumetric or gravimetric configuration. In volumetric mode the twin screw feeder runs at constant speed. Typically with difficult flowing or highly cohesive materials (such as waxes) volumetric screw feeders can have high variations in actual feed rates due to inconsistent filling of the screws which may be caused by product bridging, for example. Therefore, when used with

Metered Dry Powder Addition for Continuous and Batch Coating Processes

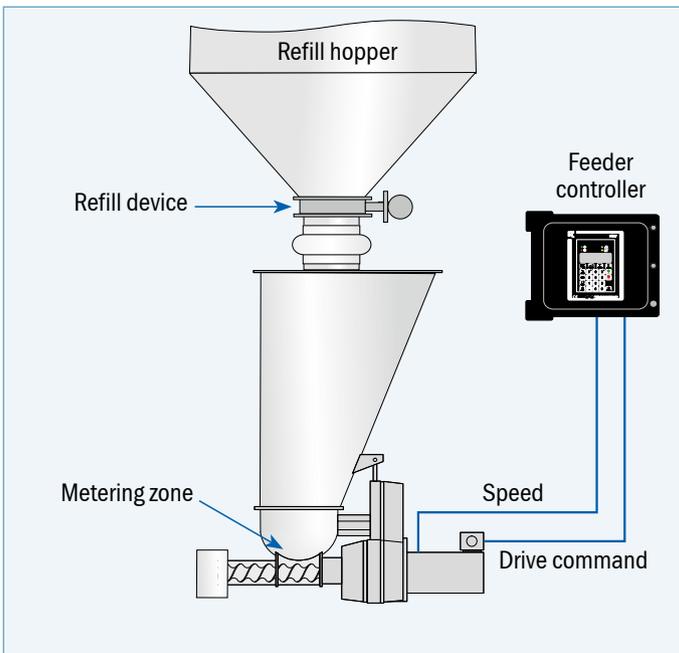
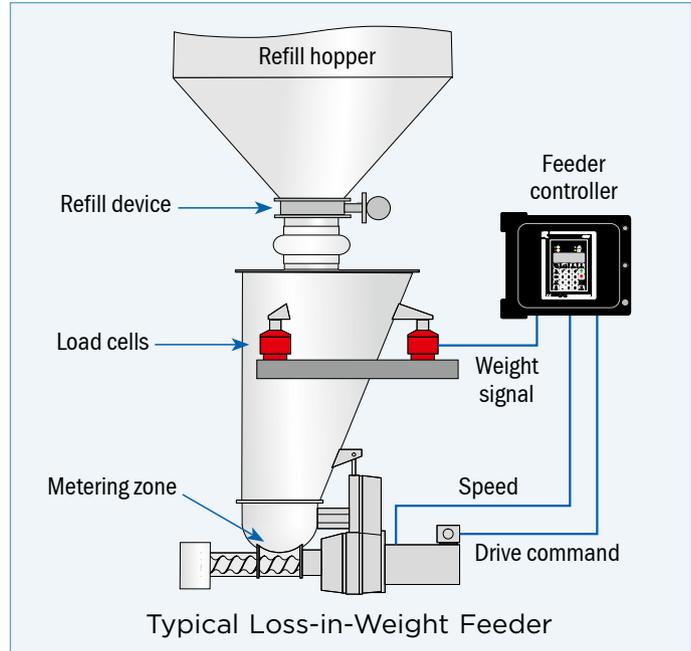


volumetric control, the constant mass flow of the powder cannot be validated.

By utilizing Coperion K-Tron's patented load cell technology, the feeder can operate in a gravimetric mode. Gravimetric mode means that the weight of the powder is continuously measured and the controls keep the weight reduction per time constant by adjusting the speed of the twin screw feeder. By adjusting the speed to maintain a consistent mass flow (or weight per time), the unit can be validated to prove a steady and uniform flow of powder is being delivered to the coating equipment. In addition, by measuring the overall material flow delivered to the coating equipment by weight, the total powder amount delivered to the coater can be calculated.

Coperion K-Tron Advantage

- Coperion K-Tron's patented SFT digital weighing technology delivers the high accuracy weight measurements needed for maintaining control of the addition of costly ingredients
- SFT's deliver a weighing resolution of 1:4,000,000 in 80 ms, and feature built-in immunity to fluctuations in plant vibration and temperatures
- All components include a quick clean, easy disassembly design complete with fully welded and polished housings and triclover clamps/ferrules
- All product contact parts are constructed to conform with strict cGMP standards



- The Coperion K-Tron Systems Group can supply integrated systems of Coperion K-Tron and ancillary products, with one source management
- Coperion K-Tron can provide all controls and engineering including CFR 21 Part 11 based control platforms
- The Coperion K-Tron Pharma feeder is designed specifically for the pharmaceutical industry, all cGMP constructed and designed, with ease of cleaning in mind

Manufacturing plants:

Coperion K-Tron Pitman, Inc.
590 Woodbury-Glassboro Rd
Sewell, NJ 08080, USA
Tel +1 856 589 0500
Fax +1 856 589 8113
E-mail: info@coperionktron.com

Coperion K-Tron Salina, Inc.
606 North Front St.
Salina, KS 67401, USA
Tel +1 785 825 1611
Fax +1 785 825 8759
E-mail: info@coperionktron.com

Coperion K-Tron (Switzerland) LLC
Lenzhardweg 43/45
CH-5702 Niederlenz
Tel +41 62 885 71 71
Fax +41 62 885 71 80
E-mail: cks@coperionktron.com