

Background

Coperion K-Tron volumetric feeders are often used in a simplified gain-in-weight (GIW) application for controlled batch dispensing and weighing of pharmaceutical powders.

Dispensing is often a step in a variety of processes including centrifuge and filter dryer discharge, batching directly into IBC's (Intermediate Bulk Containers), hoppers or drums, and batch ingredient dispensing directly into batch blenders and reactors. In the pharmaceutical industry the batched ingredients often include potent compounds, resulting in the need for a batching device that can be easily contained to eliminate any exposure of the product to the operator or to the environment.



Photo 1: Coperion K-Tron volumetric feeder with integrated ILC Dover continuous liner

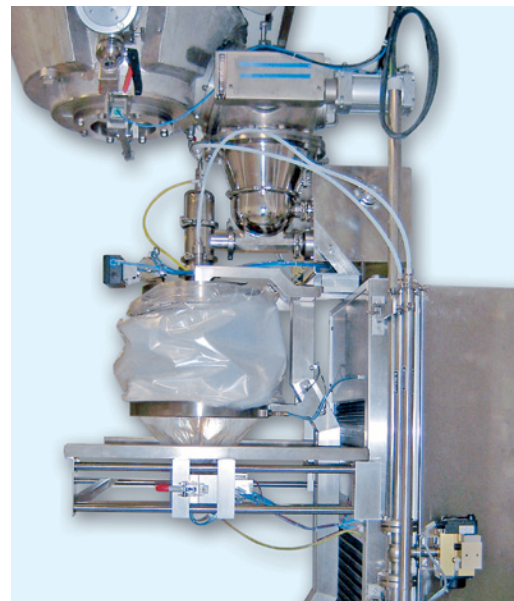


Photo 2: Coperion K-Tron volumetric feeder for batching from filter dryer discharge

Application and Process Details

In the case of photo 1, the end user utilized a portable Coperion K-Tron volumetric feeder with a modified discharge complete with an integrated ILC Dover continuous liner for easy contained bag dispensing. This unit is designed to dispense batch weights of 6, 8, and 10 kilos directly into a lined

container. Containment levels of less than 10 micrograms/m³ were achieved. Included on the portable cart design is a Mettler Toledo scale for the measurement of the batch weight. The batching program included in Coperion K-Tron's KCM feeder controller is designed for a metered flood flow of material out of the feeder until a weight is detected within 90% of the

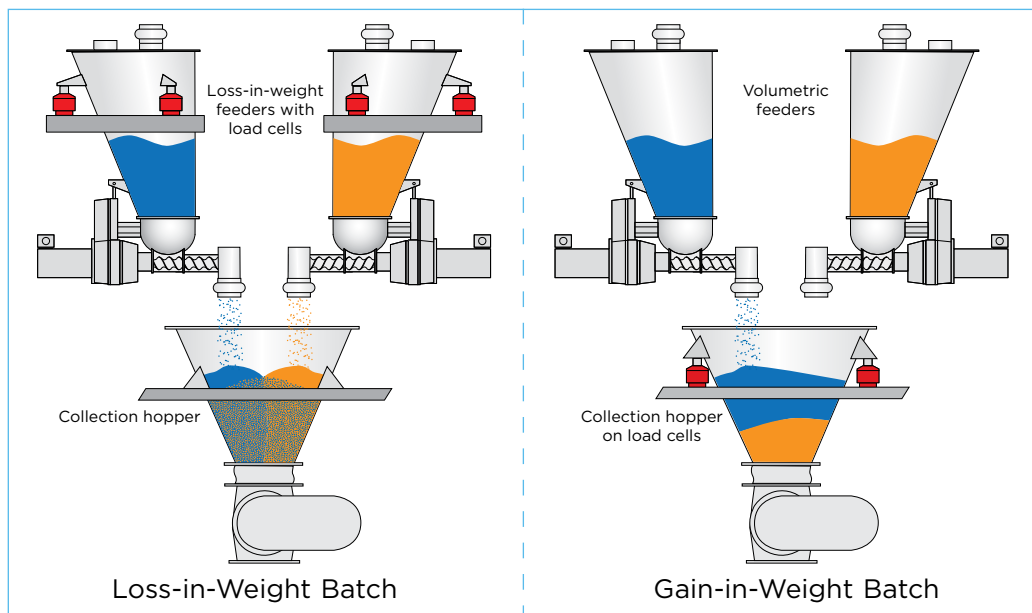
batch weight set point. When this weight signal is received by the feeder, it automatically is put into a slower "trickle feed" mode in order to accurately reach the final setpoint weight. The specialized cart is equipped with a modified jack assembly so the complete feeder inlet can be raised into position to mate directly with the outlet of the centrifuge discharge valve.

In photo 2, the same basic concept in design is supplied but with mating direct to a filter dryer discharge.

Gain-in-Weight (GIW) vs. Loss-in-Weight (LIW)

Batch size, number of materials, material characteristics and accuracy requirements will all influence which type of batching — via loss-in-weight or gain-in-weight — is best used. Typical accuracies which can be expected with the GIW method of batch weighing are +/- 0.5% of the full scale capacity.

It should also be noted that when batching multiple ingredients via GIW batching, each ingredient must be batched separately which will add to the overall process batch time. In cases where multiple products (i.e. major, minor and/or micro ingredients) are batched into larger IBC containers, a combination of volumetric and loss-in-weight (LIW) feeders may be used. The volumetric feeders are used to batch out the major ingredients first, directly into the IBC on a platform scale. The LIW feeders



Contained Batch Dispensing of Pharmaceuticals via Gain-in-Weight Technology



Comparison Chart: LIW vs GIW Batching

Requirements	LIW Batching	GIW Batching
Accuracy	0.1 – 0.5 % of batch weight setpoint	0.5% or greater of the overall capacity of the scale or load cells
Single Ingredient Batching	Best	Good – Depending upon the size of the batch versus the overall scale capacity - Highly dependent upon container size versus ingredient weight %
Multi Ingredient Batching	Best - Quickest way to batch out multi ingredients simultaneously	Good – only one component at a time
Cost	Moderate – each feeder on load cells/scale	Lower - volumetric feeders with one set of load cells/scale for receiving vessel
Containment Designs	Available	Available

are each mounted on individual weighing systems (load cells or scales), and are then used to simultaneously batch out the smaller percentage minor/micro ingredients. The scale on which the vessel is located is then used to verify the overall total batch weight of all the components. This combination of LIW and GIW technologies eliminates the requirement to batch each ingredient separately, thus decreasing the overall process batch times.

Most floor scales do not have sufficient speed and resolution to detect small amounts of

batched products relative to the larger overall weights of the IBC's, reactors or process vessels. If accuracy requirements on minors (i.e. API's, lubricants, etc.) are in the range of 0.1 – 0.5%, Coperion K-Tron LIW feeders are typically used with the feeders mounted on high speed digital load cells with 1 part in 4 million resolution. A LIW batch controller monitors material weight loss from the feeder hopper and controls the start/stop function of the feeder to control the achievement of batch weight setpoint.



Coperion K-Tron Advantage

- The Coperion K-Tron Systems Group can supply integrated systems of Coperion K-Tron and ancillary products, with one source management and integrated controls
- The Coperion K-Tron Pharma feeder is designed specifically for the pharmaceutical industry, all cGMP constructed and designed, with ease of cleaning in mind
- For batching and dispensing, Coperion K-Tron's state-of-the-art SFT digital weighing technology delivers the high accuracy weight measurements needed for maintaining control of the addition of costly ingredients
- SFT load cells and scales feature a weighing resolution

of 1:8,000,000 in 20 ms, as well as 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
- Coperion K-Tron can provide all controls and engineering including CFR 21 Part 11 based control platforms
- Coperion K-Tron can provide systems suitable for various containment and OEL levels, as well as specific cleaning and sanitation requirements
- Coperion K-Tron provides complete validation packages inclusive of system IQ and OQ documentation

