

Background

Automated dispensing systems are utilized throughout the pharmaceutical industry for the loading of excipients, active pharmaceutical ingredients (API's), and lubricants into Intermediate Bulk Containers (IBC's) and other large vessel devices. In most pharmaceutical plants, separate broaching areas are established in which the raw materials or excipients may be brought in from outside suppliers or other plant locations. These broaching areas usually include the unloading of pallets containing drums or boxes, or the unloading of supersacks. The contents of each container are transferred via either gravity flow or pneumatic transfer to the dispensary area for the loading of IBC's. Following this loading operation, loss-in-weight (LIW) feeders are used to regulate and meter the amount of these components being fed into the receiving IBC. LIW feeders are critical when utilizing small weight percentages of individual ingredients that are a fraction of the total batch weight.

Principle of Operation

Typical flow diagrams are similar to the arrangement shown in the process diagram at right. In the case of single material loading, as in excipients, the material may be conveyed under vacuum via Coperion K-Tron P-Series pneumatic conveying receivers to a separate hopper mounted above the Coperion K-Tron loss in weight feeder. In cases where a pre-mixed formulation or granulation may exist, the granulation IBC is transferred directly to the automated dispensary. The outlet of the IBC or the loader hopper is equipped with a modulating valve. This valve can consist of either a sanitary butterfly valve or a split butterfly valve, depending upon the level of containment required. If the product to be

dispensed is an API, or if the granulation of mixed formulation includes such actives to deem it as an exposure risk, then split butterfly valves are often used, both on the outlet of the feeding hopper and on the inlet or outlet of the Coperion K-Tron LIW feeder.

The LIW feeder utilizes state-of-the-art highly accurate digital load cell weighing technology to dispense the proper amount of product to the vessel or IBC below. In addition, the Coperion K-Tron refill array for feeder refill is utilized during the batching process to control the amount of refill required by the Coperion K-Tron feeder hopper. The butterfly valve at the discharge of the hopper is utilized to ensure complete isolation of the feeder outlet once the desired setpoint of material weight is reached.

In cases where several ingredients are metered into the same IBC, automated guide vehicles (AGV's) can be used

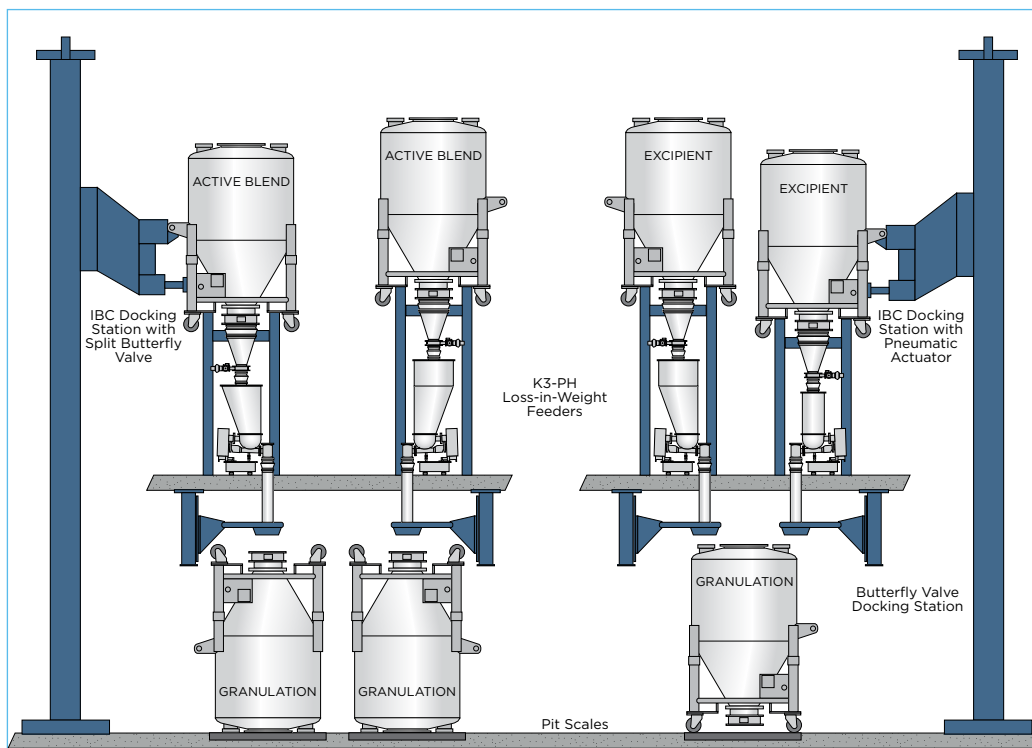
to transport the IBC between each dispensary station. The use of in-depth recipe control can be incorporated in the the Coperion K-Tron control system to ensure the proper delivery of each ingredient to the recipient IBC.

Gain-in-Weight, Loss-in-Weight, or Both?

Batch size and accuracy requirements will determine which concept is best to be used. Gain-in-Weight (GIW) concepts employ a receiving vessel mounted on load cells and typically twin screw volumetric feeders metering the material into the vessel. A GIW batch controller monitors material weight from the scale and controls the start/stop functions of the volumetric feeder. This concept can be used when the response time and resolution performance of the platform scale is sufficient enough to guarantee the accuracy requirements for



Coperion K-Tron P-Series pneumatic receiver and LIW feeder with IBC dispensary station



Process Diagram

Pharmaceutical Dispensary Applications



the batch. Most floor scales do not have sufficient speed and resolution to batch small amounts of products into large volume IBC containers. If accuracy requirements of +/- 0.1 to 0.5% are required on small batch sizes, Coperion K-Tron Loss-in-Weight (LIW) batching systems are used. This concept employs a hopper with typically a twin screw feeder mounted on a high speed digital load cell with 1:8,000,000 resolution in 20 ms. A LIW batch controller monitors material weight loss from the hopper and controls the start/stop functions of the feeder.

When additional security or verification of delivered batch weight is required, a dual weighing scenario is used. This concept employs a combination of the LIW batching system feeding into a GIW system. The GIW system is simply used to confirm the batch delivered by the LIW system prior to acceptance of the batch and further processing.

Applications for Coperion K-Tron Feeders and Pneumatic Conveyors

- Highly accurate feeding of mills and micronizers
- Feeders for granulations via hot melt extruders
- Dilute and dense phase vacuum conveying for loading and unloading of a variety of pharmaceutical processes

- Tablet Press Tooling Coating
- Feeders for solid and liquid synthesis
- Dispensary applications including IBC broaching, loading and unloading
- Continuous processing including micronization, continuous direct compression (CDC), continuous granulation
- High Accuracy, low rate feeding of active ingredients (as low as 20 g/hour)

The Coperion K-Tron Advantage

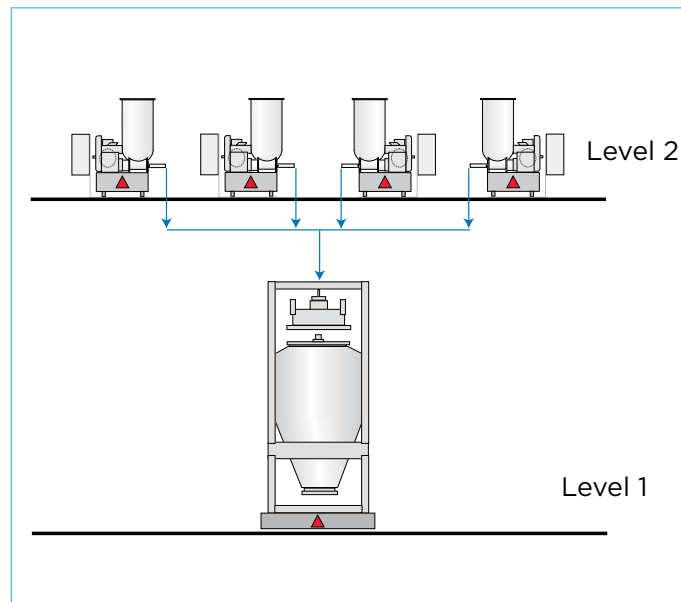
- The Coperion K-Tron Systems Group can supply integrated systems of Coperion K-Tron and ancillary products, with one source management
- Coperion K-Tron can provide all controls and engineering

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
- The P-Series line of pneumatic receivers is also designed for cleanability and ease of access, with all materials of construction FDA approved.
- Coperion K-Tron can provide systems suitable for various containment and OEL levels, as well as specific cleaning and sanitation requirements



Coperion K-Tron K3-Pharma feeder on D4 scale



LIW feeders feed various components to an IBC on a platform scale



Vacuum receiver

