Application Example

Refilling Loss-in-Weight Feeder via Pneumatic Conveying in Continuous Pharmaceutical Processes

Background

The mode of refill of product to a Loss-in-Weight (LIW) feeder that is feeding a continuous pharmaceutical process can be almost as critical as choosing the right feeder technology. Since the objective of feeder refill is to refill as quickly as possible, pneumatic receivers that operate under a dilute phase vacuum transfer principle are often used as refill devices, particularly for continuous operations. The photo on page 2 illustrates a Coperion K-Tron P-Series receiver above a Coperion K-Tron LIW feeder.

When refilling in a continuous pharmaceutical process the refill devices must reliably maintain constant flow of the Active Pharmaceutical Ingredient (API) or excipient to the process within specific refill time limits. This time limit must be relatively short, in order to allow the feeder to return to a true gravimetric operation, and ensure constant mass flow of the product to the process. Additionally, the cut-off action of the selected device must be quick and sure. A slow tapering off of the refill flow needlessly lengthens refill time. Any leakage of the refill device may cause a weight disturbance, resulting in a flow error in the positive direction. A sample flow diagram of a refill operation for a continuous blender system is shown at right.

A variety of cut-off valves may be utilized. Options include knife gates, flap valves, modulating butterfly valves, rotary valves. Butterfly valves are usually the valve of choice in the pharmaceutical industry due to their easy clean design, and also due to their availability in high containment configurations.

Principle

The pneumatic system utilizes negative pressure via a vacuum pump to suck the material required to refill into a separately mounted and supported vacuum receiver. The receiver is filled to a determined level and then holds this material charge until the feeder below requests a refill. The level of fill in the vacuum receiver is determined by level sensors. At the point of refill request by the feeder below, the discharge valve opens and the receiver contents are discharged into the feeder hopper. For LIW feeding, this discharge valve is usually a pneumatic butterfly valve in order to prevent any chance of dribbling. At the time of material release, a gas pulse is sent through the filter housed in the vacuum receiver, in order to release any entrained particulate or material that may have settled on the filter. The filter material can vary. Options include laminated membrane type materials for quick release and easy clean properties.

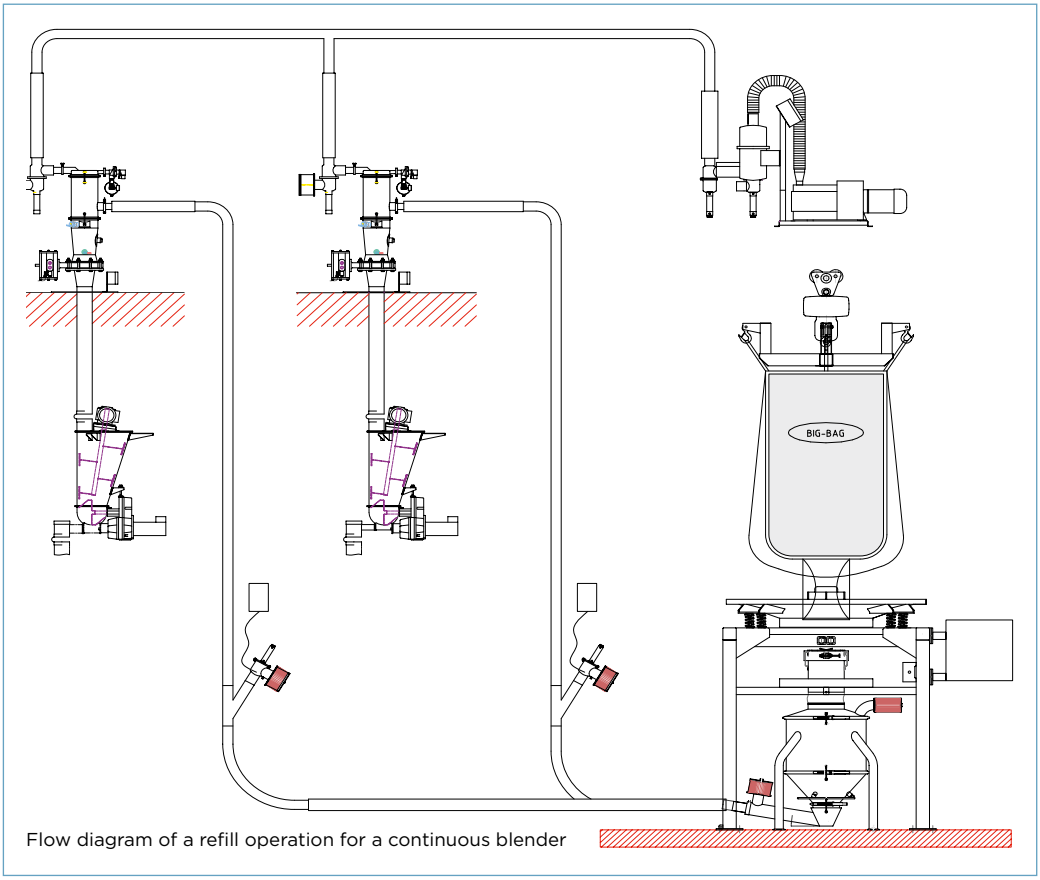
After dumping the material into the feeder hopper below, the valve is shut. The receiver vacuum cycle immediately begins again, in order to be ready for the next feeder refill request.

Coperion K-Tron P-Series vacuum receivers are often utilized for these operations due to their easy clean design. The P-Series receivers provide a custom solution for difficult conveying applications, while the sanitary design is perfect for applications in the food and pharmaceutical industries.

Product Pick-Up

Typical materials which are conveyed to the continuous pharmaceutical process can include premixed/preblended combinations of excipients, standalone excipients or API's. Depending upon the source of these components, materials can be delivered in either flexible containers (e.g. FIBC's), rigid intermediate bulk containers (IBC'S), drums or sometimes even directly from another process. The method of pickup and delivery to the vacuum receiver is determined by space limitations, ergonomics, material flow properties and also product/process containment. For example, when delivering materials with high potency occupancy exposure level (OEL), typical pickup hoppers or docking stations will include split butterfly valves for containment of the process during docking and undocking.

In each of these scenarios care must be taken as to the overall delivery of the product to the vacuum receiver. In the case of simple pickup via a stainless steel wand that is inserted into a drum, special care must be made in the design of the wand, to ensure that the liner of the



Flow diagram of a refill operation for a continuous blender

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drum does not get picked up with the product. In the case of delivery of a potent material from drums, multi-chamber drum discharge stations are often used. The chambers of these stations allow for isolation of the drum in a contained environment, opening of the lid, cutting of the liner (if applicable) and finally tipping of the drum through a valve, into the pneumatic pickup receiver below.

In all cases it is critical that the overall sequencing of the product pickup process and relative sizing of both the feeder refill hopper and pneumatic receiver allow for quick changeover of these pickup points without interruption of the process. For example, in cases with an IBC docking station equipped with a pneumatic pickup and a split butterfly valve, the time for changeover to a new bin can often be as much as 15 minutes. Refill sequencing and feeder hopper volume must ensure continuous material flow for the process and allow for lack of material delivery while these pick up components are emptied and being changed over. It is imperative with any continuous process that the overall material delivery and process feed components be tightly integrated, as the quality of the process is entirely dependent upon this coordination.

Pneumatic refill receiver above Coperion K-Tron LIW feeder

Typical Processes

The following are typical continuous pharmaceutical Processes that require pneumatic conveying refill operations for loss-in-weight feeders:

- Direct Compression (CDC)
- Granulation via Hot Melt Extrusion
- Wet Granulation
- Milling/Micronization

Coperion K-Tron Experience

The use of the Coperion K-Tron P-Series receivers coupled with Coperion K-Tron's line of high accuracy LIW feeders provides for overall process control and efficiency. Coperion K-Tron's extensive experience in the handling of a wide range of pharmaceutical excipients and API's ensures that the overall system will be designed not only with the product and operator safety in mind, but will also utilize the best material handling solutions for the process. In addition, K-Tron's ability to provide integrated controls and engineered systems solutions guarantees that the overall function of the process will operate consistently, a critical requirement for any continuous pharmaceutical process.

Coperion K-Tron Advantage

- The Coperion K-Tron Systems Group can supply a completely integrated systems approach in material handling and product delivery
- Each solution is custom developed according to the process application, based upon Coperion K-Tron's extensive experience in providing a wide range of material handling solutions
- The P-Series of pneumatic receivers are all designed with ease of cleaning and maintenance in mind
- 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 and are constructed of 316L stainless steel
- 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 can also supply a complete set of validation protocols, in accordance with the System Life cycle Approach.

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