Solutions for the pharmaceutical and biotech markets

HCVs for powders

By V Bhasin, SigmaTech

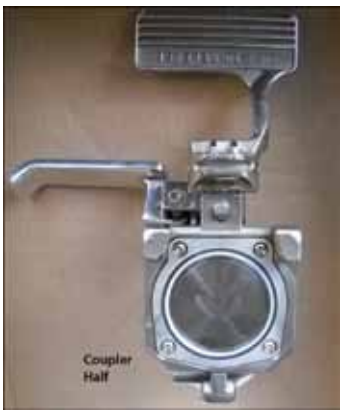
Whether you are a small-scale lab, medium sized batch processor, or large manufacturer, chances are that you are using High-Containment Valves (HCV) for processing and transferring powders.

Powders are used in the pharmaceutical plants to make Active Pharmaceutical Ingredients (APIs) for formulations and pills. Powders are also processed in the biotechnology, cosmetic and food manufacturing. Some of these powders can be quite toxic and even carcinogenic requiring extreme caution while handling and processing. If inhaled inadvertently, they can pose health risks to the personnel working in the plant. R&D and Pilot plants work largely with the more potent APIs requiring stringent OEL – Occupational Exposure Level (OEL) limits. These groups are particularly concerned with operators not becoming injured by powder exposure due to high potency and toxicity in the API. Clinical batches are like full production batches... APIs are mixed with 'excipients' and 'incipients' resulting in lower toxicity and potency; these operations are scaled up to full production.

Sanitary, HCVs are often specified to assure safe and secure transfer of hazardous powders. To understand how a typical transfer of powders in a batch works, this is an overview of the transfer process: A HCV consists of two halves that are 'latched' together to form a connection to transfer powders. The top half is connected underneath a hopper where powder is gravity fed into the hopper. The bottom half is connected to a movable container into which the powder is deposited. To transfer powder, it is essential that the two halves are connected securely to each other. To start the transfer, the HCV is first opened and then closed using a flow control handle. Once the transfer of a batch of powder has been completed, the two halves are separated ('unlatched' from each other), and a new container is latched onto the bottom half of the HCV.

This process of latching and unlatching is repeated over and over again until all batches are transferred. It is extremely important that during unlatching of the two halves, no spillage except a minute amount occurs.

HCVs are generally available in sizes 1" (DN 25) through 12" (DIN 200). The smaller sizes (1/2" through 3") are used in research and development (R&D) labs and pilot plants to produce clinical trial batches. Larger sizes (4" through 12") are used for large capacity batch production. HCVs are available based on essentially three designs: poppet valve, ball valve, or a butterfly valve. The most commonly used HCVs are of split-butterfly valve design. By nature, valves based on poppet or a ball valve cannot be considered sanitary because they can trap powders during the transfer operation. A poppet valve will always contain some dead volume of powder, no matter what, and a ball valve design allows certain dead space between the ball and the body. Most user complaints with poppet and ball valve designs are leaky valves and requiring unacceptable high force for valve operation, and high maintenance costs. Compared to valves used with liquids, powders do not provide any lubricity leading to higher operating force.



Coupler half of the valve.

HCVs based on a split-butterfly valve design address many of the above deficiencies. One of the author's companies is a leader in making such valves (dry-disconnect couplings) for the liquid market. Dry Link, Inc. now offers the same split butterfly containment technology for dry powder transfers. The HCV features a split butterfly valve design consisting of two halves of a body. Two identical, thin-profile disc halves rotate in unison to create an excellent flow path.

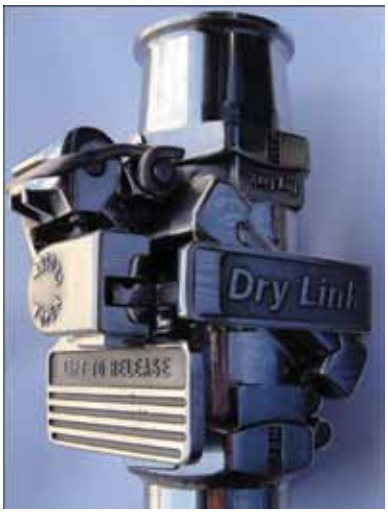
A single flow-control handle opens both halves simultaneously. A patented triple sealing design ensures clean, secure and safe product transfer. Built-in safety interlocks prevent accidental separation. The smooth bore has no voids, dead spaces, crevices, or fillers to trap material. Efficient cleaning can be done using CIP/SIP methods. The coupler half and the adapter half are bidirectional meaning that either half of the valve can be used as Active or Passive. This valve is extremely tight and requires a low operational force. HCVs are available in SS316 and Hastelloy C materials with PTFE Seals with wide choices of end-connections (female threaded end, butt-weld end, flanged end, Triclover end, etc.), although a sanitary Triclover end connection is the most common. Dry Link recommends all internal surfaces to be polished to 20 RA micro-inch (0,5 RA microns) smooth finishes to minimise adhesion of solids to the valve

Adapter half of the valve.

and to reduce operational force. These valves have fewer internal components resulting in low maintenance. Valves can be supplied with removable dust covers.

Conclusion

There are many types of HCVs available in the market. These valves must be selected based on seal tightness, low OEL, ease of operation, and low maintenance. Many companies make claims of unrealistic low OEL that are based on controlled testing by independent testing labs. The prototypes submitted for testing may not represent actual production valves. The user should be wary of such claims and conduct their own testing and evaluation to suit their application. Expecting and imposing unrealistic low OEL for HCVs can be disappointing.



HCV (the two halves of the valve shown in the latched position).

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About the author

- Many applications require the transport and management of powders in the process.
- High Containment Valves (HCVs) are required to ensure safe and secure transfer of powders.
- HCVs must be selected based on seal tightness, low OEL, ease of operation and low maintenance.

Take note

API – Active Pharmaceutical Ingredients.
CIIP/SIP – Cleaning-In-Place/Sterilisation-In Place
HCV – High Containment Valves
OEL – Occupational Exposure Level

Abbreviations

ROUND UP

Ported 'knife gate' valve

One of the most common mistakes in the mining sector is that metal seated knife gate valves intended for the pulp and paper industries, are used instead of valves more suited for such robust applications due to their price, and the salesperson not understanding their clients application. OMSA offers ported knife gate valves specifically designed for heavy slurry applications.

Made from ductile iron, making it more affordable than the traditional stainless steel option, OMSA offers the ITT C133R ported knife gate valve, suitable for heavy, medium and light slurry operations.

Greg Hopton , sales manager at OMSA said, "OMSA believes that there are two crucial elements that customers require in the slurry industry, namely maximum plant availability and quickest return to service when a valve has to be replaced, and the ITT C133R offers exceptional quality and value and meets those two requirements handsomely. The valve can operate up to 95°C, which covers most slurry applications. It has specially designed body liners that have a patented reinforced seat energiser, keeping the gate in check at all times during opening and closing procedures and among other features has locking pins with a double-function: acting as a lock out safety feature when the valve is out of service, and to ensure that the valve is either fully open, or fully closed therefore eliminating wear on the gate. While the valve is available in the less expensive ductile iron OMSA will be offering the valve in all materials to suit all applications."

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Butterflies spread their range

The new **GEMÜ** D480 wafer pattern butterfly valve is available in nominal sizes DN 25-1400. A wafer type version, an end-flange version with threaded holes and a double flange version are available body configurations. The installation length is in accordance with EN 558-1 basic series 20. Connection standards to DIN (PN 10/16), ANSI 150, JIS and BS can be supplied. Standard pressure ratings are 10 bar and 16 bar. A soft-sealing concentric version of the D480 butterfly valve is suitable for pressures up to 25 bar. The butterfly valve complies with the safety requirements of Annex 1 of the European Pressure Equipment Directive 97/23/EC for fluids of group 1 and 2. A wide range of materials and coatings is available for the body and butterfly disc extending from SG iron to super duplex steels. Coating materials are Resicoat, Rilsan or Halar.

The seats are available in 17 different versions from EPDM to Viton (FPM). These include an FDA compliant EPDM and a version for drinking water. The drinking water version fulfills the requirements of ACS, KTW, WRAS and W270. Exchangeable seats or seats vulcanised to the body can be supplied. Vulcanised seats are particularly suitable for applications involving high pressures, mechanical stress and vacuum.

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