

Valves for Pharmaceutical applications

Some of the more prevalent challenges facing the Pharmaceutical industry are:

- ▶ Contamination
- ▶ Dead Space
- ▶ Leakage to Atmosphere
 - Stem leakage
 - Lethal service
- ▶ Tight Process shut off
- ▶ Crystallisation – Crust formation
- ▶ GMP – to prevent product cross contamination
- ▶ Fire Safety
- ▶ Temperature Measurement
- ▶ Sampling

Contamination

To avoid the possibility of contamination and remnants in gaps, manufacturer provides stationary FDA approved O ring seals. Single part seat, body and disc spindle

construction ensure that the all parts of the valves interior can be cleaned and sterilised. All inner parts of the diaphragm valve can be enclosed in the rubber diaphragm to ensure that the valve is totally sterilisable.

Figure 1 (illustrates a typical glass/

PTFE lined disc bottom outlet valve used by the pharmaceutical industry. These valves come with a number of features including emergency manual override, side mounted actuation (to save space), and bellows to ensure zero leakage to atmosphere.

Dead Space

All valves are fitted exactly to the reactor nozzle to ensure that there is no dead space at the bottom of the reactor which might not take part in the mixing process. The valves are designed to allow the vessel and themselves to drain completely.

Media containing solids and crystals

Disc valves are compact, offer positive sealing and feature automatic crust breaking on disc rising versions. However a piston valve may be preferred on large reactors as the

Large gap for CIP | GMP O-RING | GMP Lip seal | Expandible seat

drainage time may be reduced by up to 5 minutes, allowing more batches to be produced. Because the piston withdraws completely out of the flow path, they are also better able handle large crystals which may get stuck between the disc and the seat. Piston valves are available with either radial or metal to metal sealing surfaces.

Sealing to outside

To eliminate leakage to the outside, all disc rising valves can be fitted with either a PTFE extruded bellows a metal bellows or a PTFE or rubber diaphragm. These seals are also available for disc lowering valves. In all cases an emergency the stuffing box provides security in the event of a seal failure.

All Disc valves have an FDA approved PTFE sealing ring and a fire-safe metal back up seal:

An insert into the nozzle is usual for disc valves. The gap between insert and nozzle can be fitted with a CIP connection and flushed out between different batches, or else can be closed off from the process in the vessel using either an O-ring, a lip seal or an expandible seat.

Clean-in-place

All valves can be fitted with flushing ports allowing cleaning of the valve while a reaction is taking place in the reactor.

Temperature sensing

Placing a temperature sensor in the

valve disc or piston ensures that the reactor's contents can be measured even when the batches are very small. In addition, a nozzle and space at the top of the reactor is saved by this arrangement. The sensor leads can be terminated in a junction box on the yoke or under the actuator. Here the advantage is that the probe can be removed for calibration or replacement while the reactor is charged.

The measuring probe is placed in the tip of the device and a small spring ensures that the probe is pressed against the inner side of the disc or piston, which has been machined to only 1-2mm thickness. As the probe is inside the disc, there can be no leakage to the outside. Accurate measurements can be obtained with response times of approximately one minute.

Fire-safety