Valves for the Pharmaceutical and Fine Chemical Industries

SchuFl

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SchuF is fully registered, accredited and certified worldwide

Valves for the Pharmaceutical and Fine Chemical Industries

Overview

In recent years, the dual pressures of rationalisation and safety/environmental regulations have driven technical progress in the pharmaceutical and fine chemical industries, resulting in a number of significant developments. SchuF, which has partnered many of the world's leading pharmaceutical companies in this field, have been at the forefront of these innovations for many years, and continue to investigate new possibilities while refining and improving existing products.

The major concerns of manufacturers and processers working with pharmaceutical intermediates and other fine chemicals include:

- Process Analytical Technology (PAT)
- Elimination of dead space and cross-contamination issues, in line with GMP compliance
- Zero leakage to atmosphere, including lethal service requirements
- Firesafe Certification
- Absolute positive shut-off, Leakage Rate Class VI
- Ability to handle media crystallisation and crust formation
- FDA compliance
- Clean-In-Place (CIP) capabilities
- Temperature measurement, even in low volume batches
- Efficient, safe sampling
- Internal surfaces polished to Ra < 0.2µm
- Additional sensor functions

Each and every SchuF pharmaceutical valve addresses these concerns while demonstrating the industry-leading combination of such time-proven qualities as robust construction and reliable operation. In addition, the customer benefits from SchuF's innovation-friendly approach, which continuously leads to the utilisation of new materials, more efficient operational designs, and an expanding range of multiple-function capabilities.

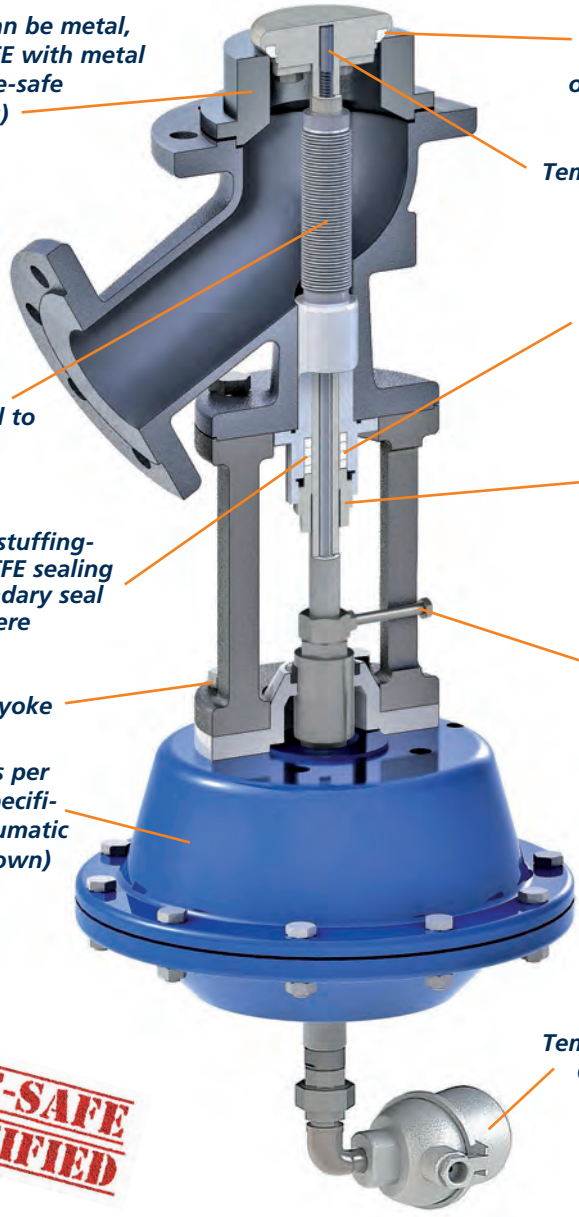
Disc Bottom Outlet Valves – St. St., Hastelloy and other Alloys

Features

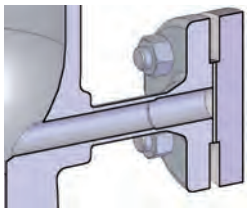
Type 25

SchuF flush-mounted bottom outlet valves see extensive service in the bulk pharmaceutical and fine chemical industries. They are often used in the production of core active-ingredient acids and vitamins.

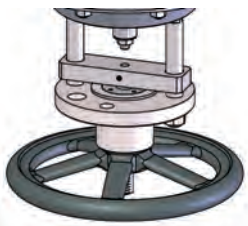
The Type 25 bottom-outlet Valve in Stainless Steel, Hastelloy (or other alloy) body and trim provides a solution where customers require a flush-mounted, custom-fit valve with high corrosion resistance and complete operational reliability in order to maximise their system's high-level functionality. Bespoke design requirements can be incorporated into each valve alongside tried and tested standard design features, such as **elimination of dead-space** in the vessel outlet, **FDA** and **GMP compliance for disc valves, full cleaning capability** together with being **flushable in place** and **fire-safe certified**. Additional options include **flushing/purging connections, internal and external polishing, positioners, limit switches, solenoid valve(s), 'seat-less' disc valve construction, CIP / GMP, manual over-ride actuator, 'T'– or spool-piece connection, leak detection, disc-grinding, jacking bolts, disc contouring, tapered seats, live-loaded packing** and **spindle wipers**.



Stuffing-box seal to atmosphere (Type 25BS) – shown here with PTFE spindle wiper



CIP (Clean In Place) option- Flanged connection shown



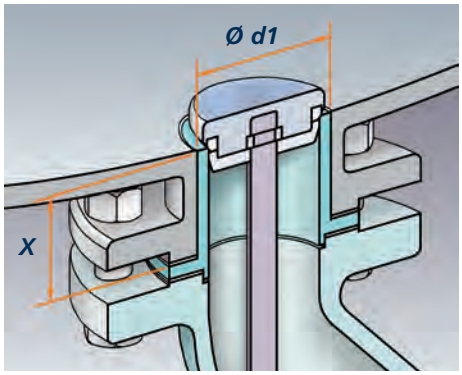
Manual override for pneumatic actuator

Disc Bottom Outlet Valves – St. St., Hastelloy and other Alloys

Standard Dimensions for common valve sizes

Type 25BS/BH

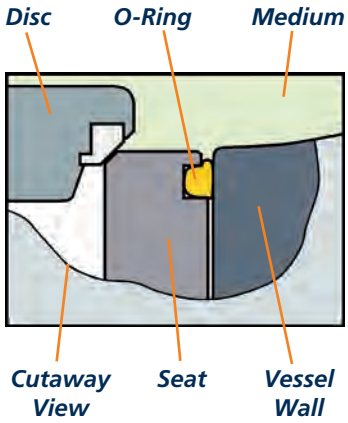
Dimensions for other sizes available on request.



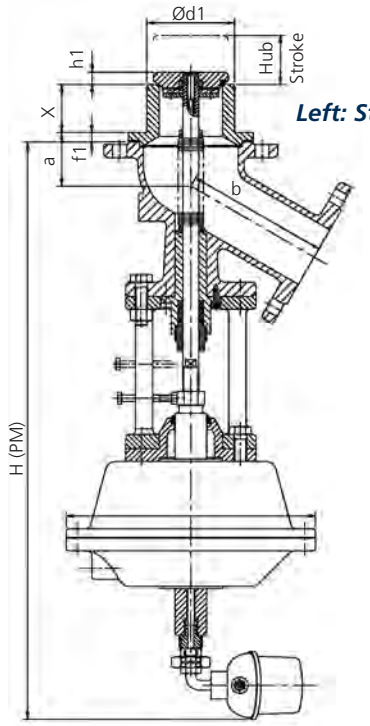
Left: The valve seat is custom-fit to match the vessel bore dimensions.

The external diameter of the seat (d1) is one millimetre less than the vessel bore.

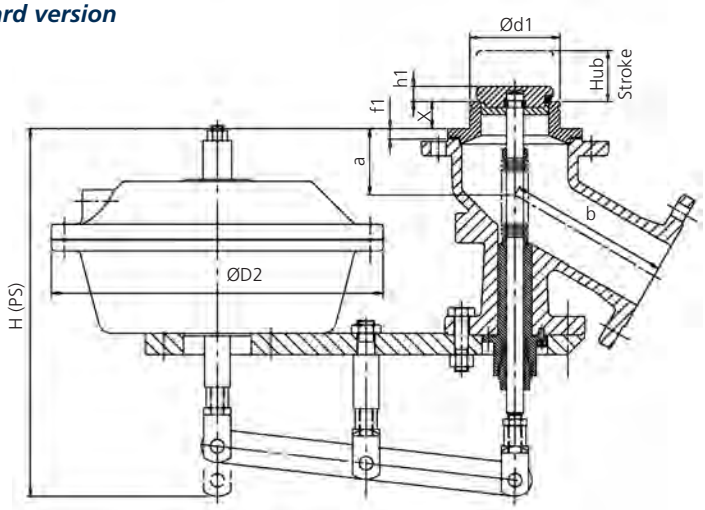
The height of the seat (X) will also match the seat and allows for a gasket seal between the seat and the vessel.



Above: GMP O-ring seal between seat-top and vessel wall



Left: Standard version



Above: Low-profile version with side-mounted actuator

Valve dimension table for Disc BOV types 25BS/25BH, with PM

	60°					45°				
Size Imperial	50/40 2"/1½"	80/50 3"/2"	100/80 4"/3"	150/100 6"/4"	200/150 8"/6"	50/40 2"/1½"	80/50 3"/2"	100/80 4"/3"	150/100 6"/4"	200/150 8"/6"
X Standard	35	35	35	40	40	35	35	35	40	40
d1 Standard	69	94	129	179	233	69	94	129	179	233
a	70	72	74	87	103	62	53	69	68	107
b	149	147	209	209	250	173	214	255	279	321
h1	11	12	18	18	24	11	12	18	18	24
H (PM)	687	692	752	772	879	761	707	775	798	955
H (PS)	360	365	425	445	510	434	380	448	471	586
Stroke	30	35	35	35	45	30	35	35	35	45
Ø D2	315	315	315	315	390	315	315	315	315	390

All dimensions are in mm unless otherwise stated. Dimensions for other BOV models/actuators are available on request.

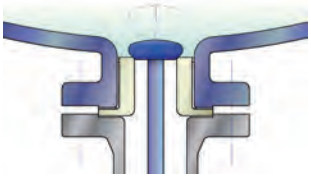
Bottom Outlet Disc Valve – Glass / PTFE / PFA-lined Body

Features

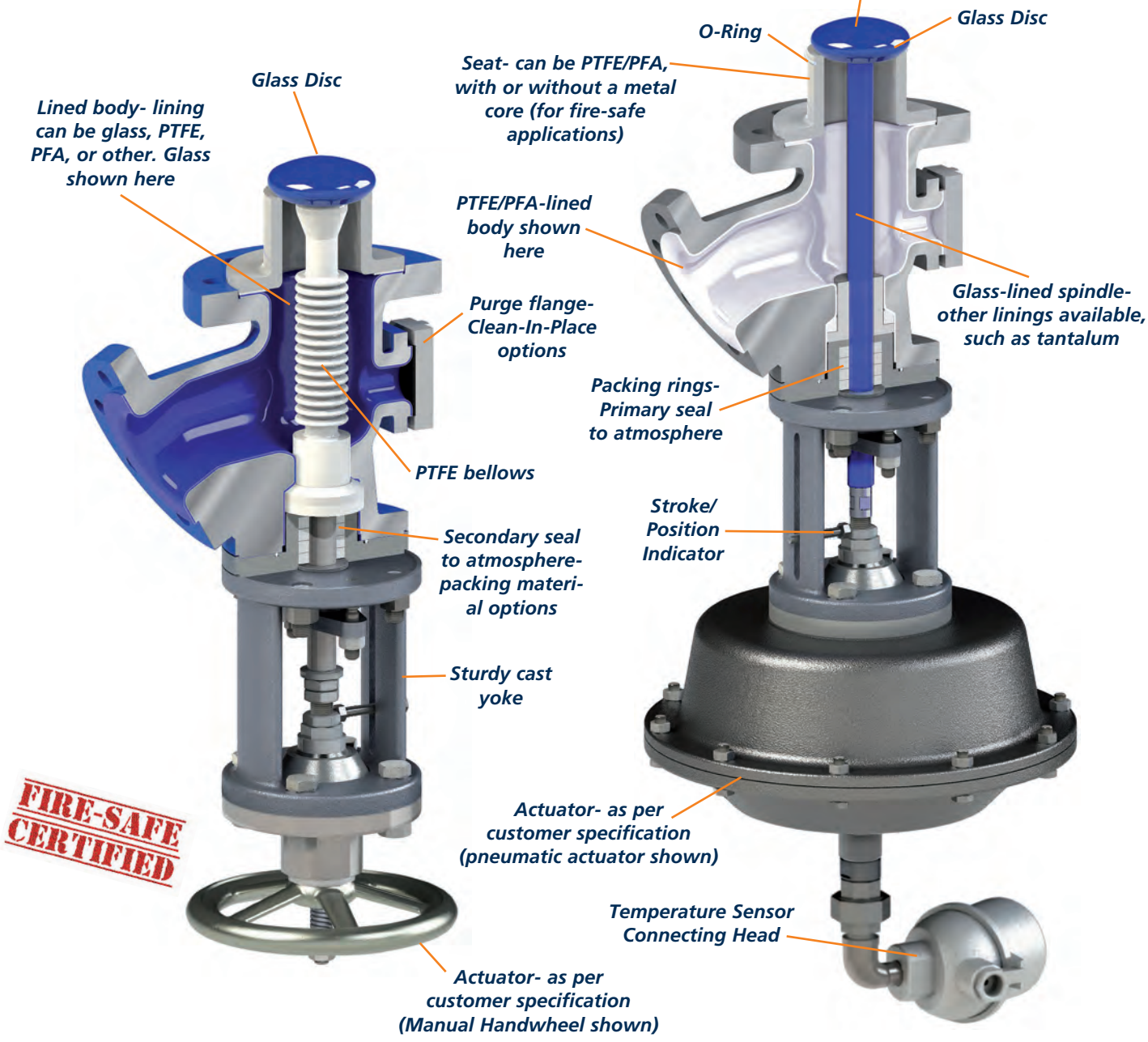
Type 25

SchuF flush-mounted bottom outlet valves see extensive service in the bulk pharmaceutical and fine chemical industries. They are often used in the production of core active-ingredient acids and vitamins.

The Type 25 bottom-outlet valve with lining in glass, PTFE/PFA, tantalum, or other materials such as rubber, provides the ideal solution when customers require a flush-mounted, custom fitted valve with high corrosion resistance and complete operational reliability in order to maximise their system's high-level functionality. Bespoke design requirements can be incorporated into each valve alongside tried and tested standard design features, such as **elimination of dead-space** in the vessel outlet, **FDA** and **GMP compliance, full cleaning capability (Clean In Place, CIP)** and **fire-safe certification**. Valves can be supplied with **bellows** or **stuffing-box** seal to atmosphere.



Seat Options: Both valves on this page shown with **standard glass** disc and **standard raised seat**

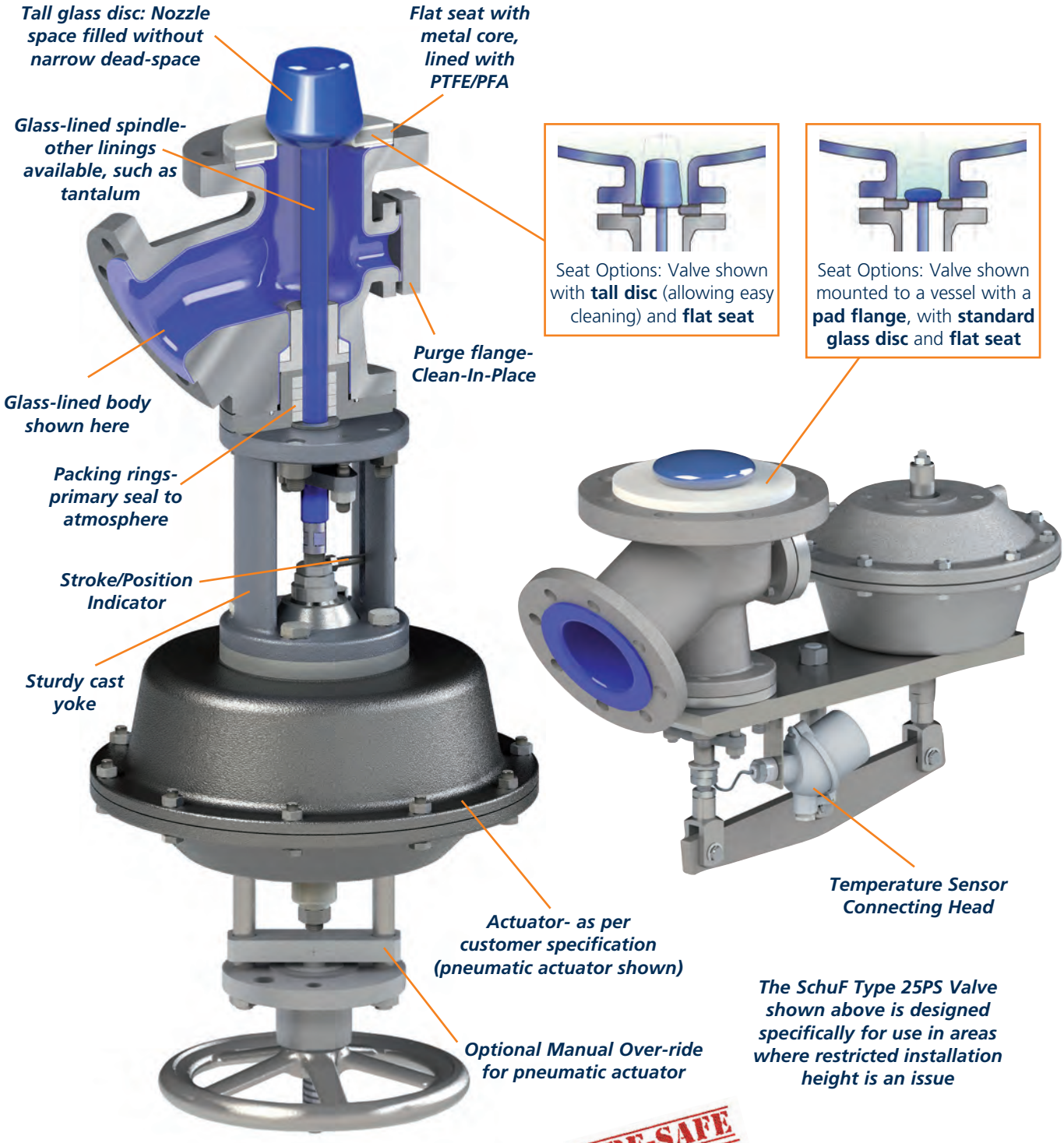


Bottom Outlet Disc Valve – Glass / PTFE / PFA-lined Body

Features

Type 25

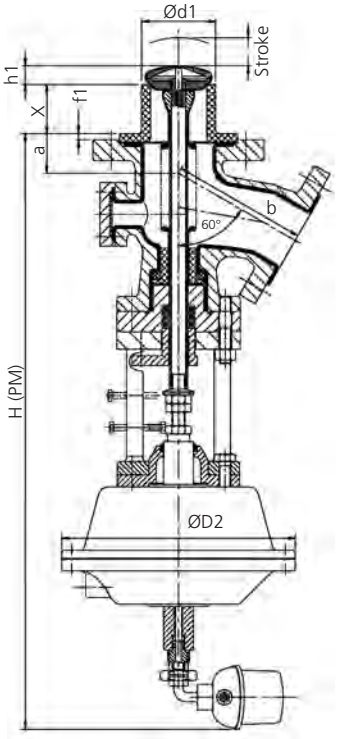
Additional options include **temperature/PAT sensors,** accessories such as **positioners, limit switches or solenoid valves, actuator manual over-ride, leak detection and live-loaded packing.**



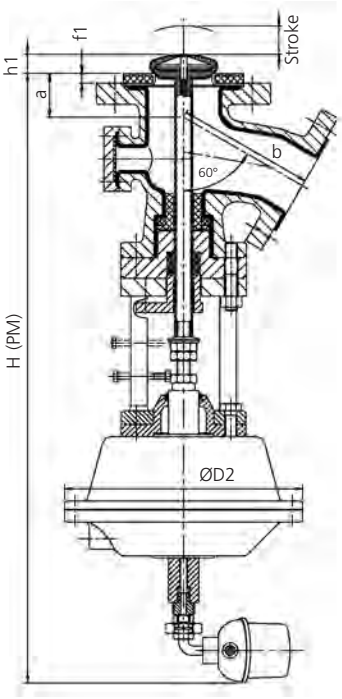
Bottom Outlet Disc Valve – Glass / PTFE / PFA-lined Body

Standard Dimensions for common valve sizes

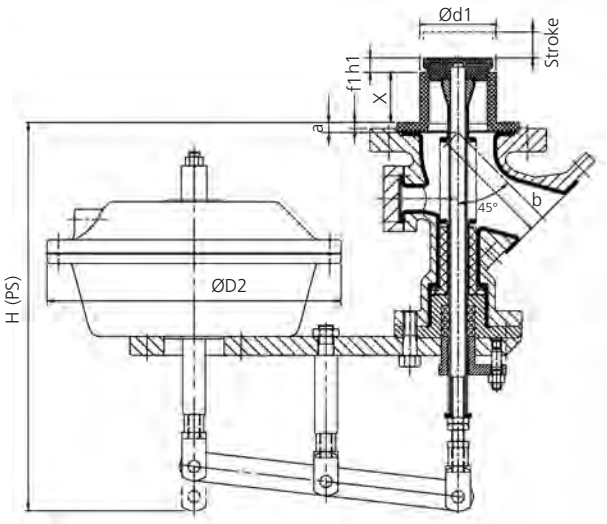
Standard seat and actuator



*Flat seat with standard actuator**



Standard seat with side-mounted actuator



Dimensions for other sizes available on request.

*Note – Variables 'X' and 'd1' not applicable for flat-seat valves.

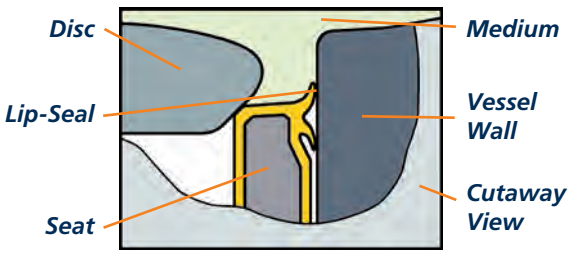
Valve dimension table for lined Disc Bottom Outlet Valves, with standard Pneumatic Diaphragm Actuator

	60°					45°				
Size Imperial	50/40 2"/1½"	80/50 3"/2"	100/80 4"/3"	150/100 6"/4"	200/150 8"/6"	50/40 2"/1½"	80/50 3"/2"	100/80 4"/3"	150/100 6"/4"	200/150 8"/6"
X Standard	50	52	66	81	min 40	50	52	66	81	min 40
d1 Standard	49	79	99	148	min 190	49	79	99	148	min 190
x min-max	30 - 75	52 - 100	66 - 150	81 - 180	40 - 180	30 - 75	52 - 100	66 - 150	81 - 180	40 -180
a	94	57	55	75	110	43	14	14	14	65
b	160	167	180	200	240	160	115	155	175	330
h1	17	18	25	23	42	17	18	25	23	42
H (PM)	630	710	790	790	875	630	710	820	840	850
H (PS)	475	480	480	500	700	475	480	510	550	675
Stroke	30	35	35	35	45	30	35	35	35	45
Ø D2	315	315	315	315	390	315	315	315	315	390

All dimensions are in mm unless otherwise stated. Dimensions for other Bottom Outlet Valve models/actuators are available on request.

Right: GMP Lip-Seal between seat-top external face and the vessel wall. The lip is pressed outwards by the vessel pressure and provides a seal against the inner wall of the vessel bore.

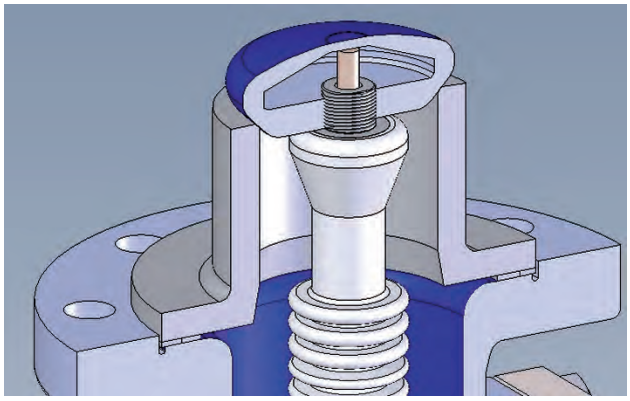
Note: The option of an O-ring seal in this location is also available



Additional Sensor Options

Temperature Sensor Functions

- SchuF Bottom Outlet Valves can be supplied with temperature measurement capability as a standard option.
- Retro-fit of existing valves is possible.
- 2xPT100 RTD, 4-wire, Class 1/3B sensors can be integrated into the disc and spindle to provide continuous real-time temperature measurement of the medium.
- The sensors are fitted at the medium's lowest point.
- No additional vessel nozzles are required.
- In many cases the sensor can be removed for calibration without removing the valve from service.
- Transmitters and connection heads supplied according to customer requirements
- The sensor cables can be routed out through the side of the valve in the yoke area, or through the actuator at the base of the valve. In either case, a connecting head with transmitter can be supplied at this point.
- The disc can be supplied with a tower to further increase accuracy and reaction time of the temperature measurement. With glass-lined discs, a tower can be supplied in tantalum.



Glass Disc with integral Temperature Sensor

Glass Disc with Temperature Sensor underneath a tantalum cap

Metal disc with integral Temperature Sensor in extended tower

Lining Integrity Monitoring

The integrity of the glass lining of a reactor vessel is of crucial importance and it is vital that any damage to the lining is discovered and evaluated as quickly and accurately as possible. Schuf supplies glass discs which have such monitoring capability via two electrodes on the top surface of the disc.

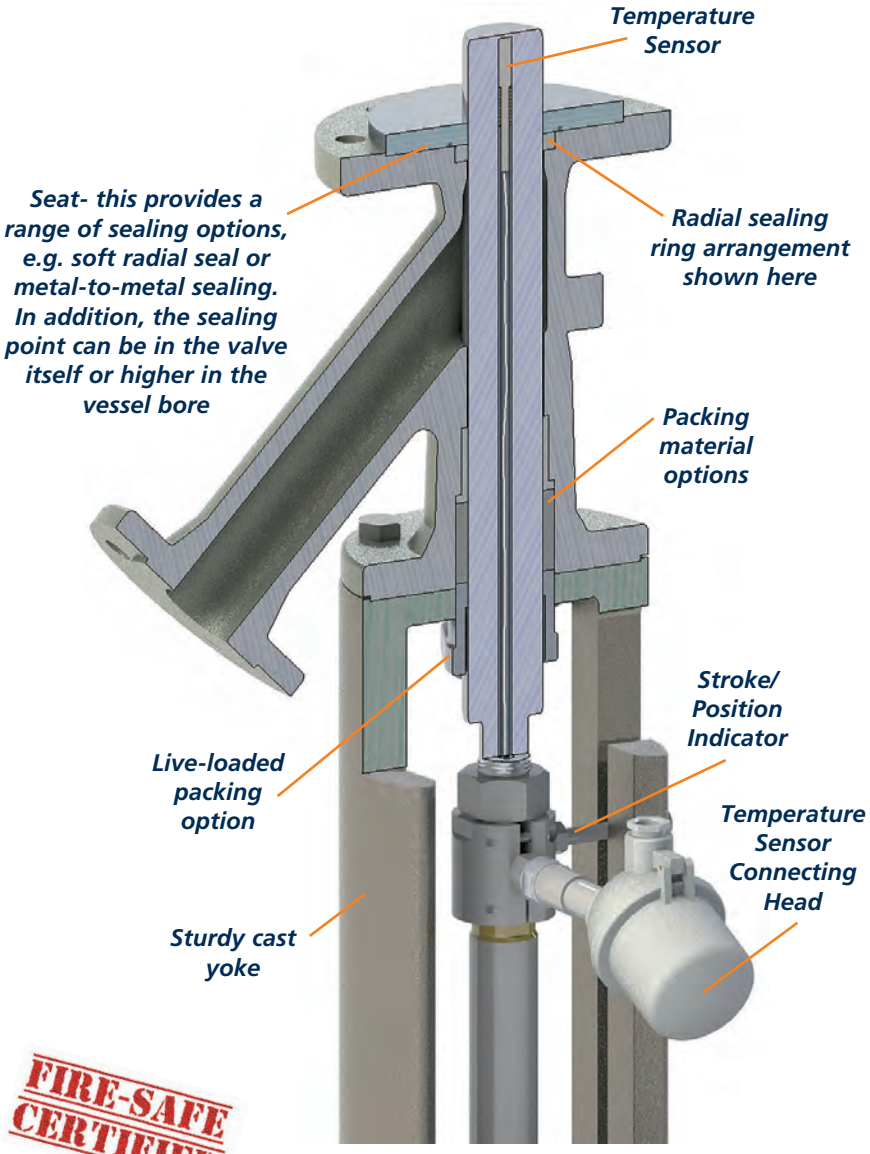
Please contact us for more information on this feature.

Ram Bottom Outlet Valve – St. St., Hastelloy and other Alloys

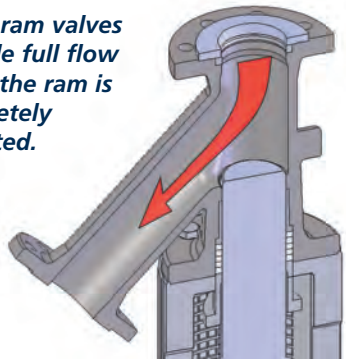
Features

Type 28

SchuF ram valves have seen extensive service in the bulk pharmaceutical and fine chemical industries, handling both liquid and powder media. They are often used in the production of core active-ingredient acids and vitamins. The Type 28 Bottom outlet valve with Stainless Steel, Hastelloy (or other alloy) body and trim (PFA lining is also possible) provides a solution where customers require a flush-mounted, custom-fit valve with high corrosion resistance and complete operational reliability in order to maximise their system's high-level functionality. Bespoke design requirements can be incorporated into each valve alongside tried and tested standard design features, such as **full-stroke open flow, elimination of dead-space** in the vessel outlet, **GMP compliance for ram valves, full cleaning capability** together with **being flushable in place** and **fire-safe certified**. Additional options include **flushing/purging connections, internal and external polishing, positioners, limit switches, solenoid valve(s), manual over-ride for powered actuators, 'T'– or spool-piece connection, leak detection, jacking bolts, ram contouring, tapered seats,** and **live-loaded packing**.



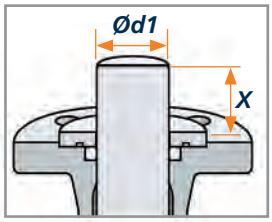
SchuF ram valves provide full flow when the ram is completely retracted.



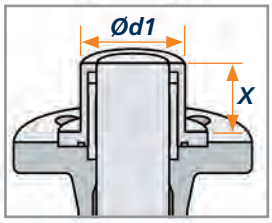
The SchuF ram valve seat is custom-fitted to match the vessel flange dimensions.

The seat 'd1' diameter is 1mm less than the vessel bore, and the seat height 'X' matches the bore height.

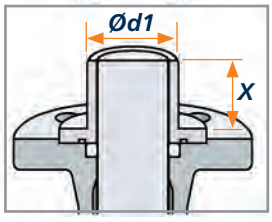
Radial seal in valve body



Radial seal in vessel bore



Radial seal in valve body, seat with custom Ød1



Bottom Outlet Valves – Draining and Sampling Systems

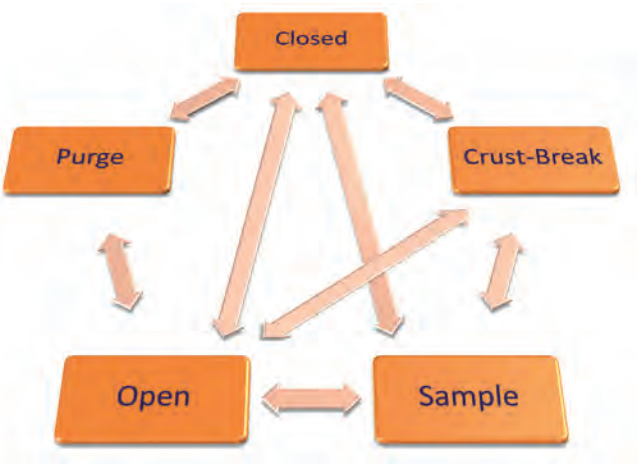
Multiple Benefits

Type 28 & 30 Series

SchuF offers a number of draining and sampling systems which operate through a single valve connection point. For example, Schuf supplies a combination of a ram-type drain valve with an integrated laterally mounted wafer-type sampling valve, Type 28PF.

Advantages of this system include:

- No need for an extra, dedicated vessel port for sampling
- Unused sample is simply returned into the vessel – no waste
- Crust-breaking facility available
- Gravity feed, no need for vacuum or Nitrogen
- No submerged piping which can become blocked
- Large sample diameters for crystals
- Sample volume control with dead-man's handle
- Exact amounts trapped in sample cavity
- An additional flush-valve prevents cross-contamination

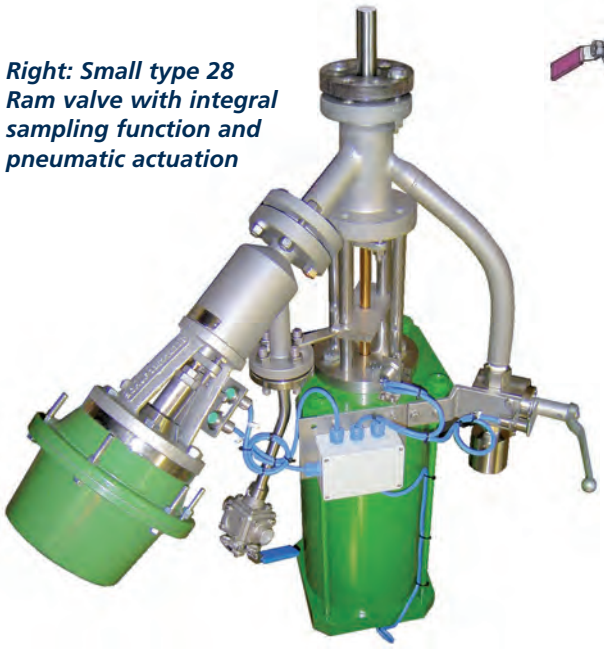


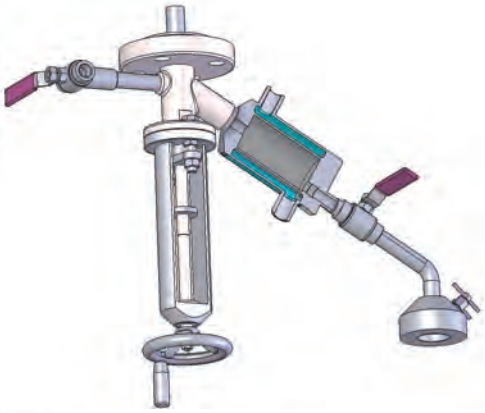
Above: The type 28PF sampling system allows a variety of operational steps to be carried out in any sequence, with repetitions as required- for example, multiple sample-taking before valve is opened and product released to the next stage

If space is at a premium, it is possible to combine wafer-type sampling valve with a disc valve in a patented SchuF combination, the Type 25PF. This valve is a shorter, more compact, lower-cost version which still features the sampling and crust-breaking capability.

Right: Large type 28 Ram valve with integral sampling function and pneumatic actuation

Right: Small type 28 Ram valve with integral sampling function and pneumatic actuation





Above: Sampling Valve with repeatable fixed-volume sampling capability, with heating (or cooling) chamber and purge

SchuF

Process Analytical Technology

SchuF Patented MultiProbe™ Valve for PAT Applications Type 25X

PAT Applications in Pharmaceutical Reactors

In recent years, there has been a significant increase in the use of Process Analytical Technology to optimise pharmaceutical and fine chemical manufacturing processes. Chemical processes can be monitored with fully-immersed PAT tools such as infra-red (IR), Raman, FBRM, and PVM probes, where direct insertion into a reactor vessel is required. Reactions can be analyzed in real time with PAT tools, providing immediate data on critical process control parameters (such as reaction initiation/endpoint, reaction progression, intermediate formation, concentration, yield, etc.).

If problems arise during the reaction, parameters can be modified before the batch is completed. The aim is therefore to reduce production cycling time and eliminate product sampling, prevent rejection of batches and to improve energy, material use and overall efficiency.

Challenges facing the Customer

A major challenge in the use of PAT is the lack of suitable entry points to introduce the measuring technology into reactors. The modification of existing vessels is prohibitively expensive, requires revalidation and is sometimes not even permitted. Entry from the reactor top can also be a problem for low volume batches.

SchuF has developed a patented, innovative, cost-effective solution to overcome this problem.

The SchuF PAT Solution-MultiProbe™ Reactor Bottom Outlet Valve (Patented):

SchuF has long been the market leader in drain valves for pharmaceutical and fine chemical applications, leading the way with deadspace-free, GMP-compatible designs, bellows sealing to atmosphere and **fire-safe certified valves**. Now SchuF enables customers to incorporate PAT technology into a reactor bottom outlet valve with built-in PAT probe monitoring capabilities. The PAT probe is installed through the valve actuator, stem and disc and is directly exposed to the medium in the reactor.

Process Analytical Technology

SchuF Patented MultiProbe™ Valve for PAT Applications Type 25X

Technical Features:

SchuF's unique MultiProbe™ patented design ensures that the medium in the reactor does not leak through the valve stem.

The PAT probe can be removed quickly between batches without the need to remove the valve from the vessel. As the PAT probe is located in the bottom part of the vessel, even low volume batches can be monitored in real-time.

Integrating PAT technology with the SchuF valve eliminates the need to modify existing reactor vessels. It is a low-cost solution, allowing the implementation of modern PAT technology in both existing and new reactors. A wide range of materials is available, including Stainless Steel, Hastelloy, Glass-Lined, PTFE-Lined and Tantalum Clad valves.

The MultiProbe™ Valve – an extremely cost-effective solution:

- No need to modify reactor vessels
- Reduced batch cycle time/product sampling
- Improved product quality
- Improved energy and material use
- Increased process robustness
- Easy installation and maintenance

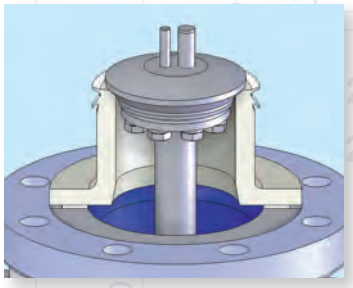
The single-shaft version accommodates one PAT probe. The Infra-Red PAT probe shown here incorporates a 1xPT100 temperature sensor

The dual-probe version utilises two shafts, one for a PAT probe and one for a standard 2xPT100 temperature sensor- each instrument can be installed or removed independently of the other

SchuF Patented MultiProbe™ Valve for PAT Applications Type 25X

The following PAT Probe types have previously been utilised in SchuF Valves:

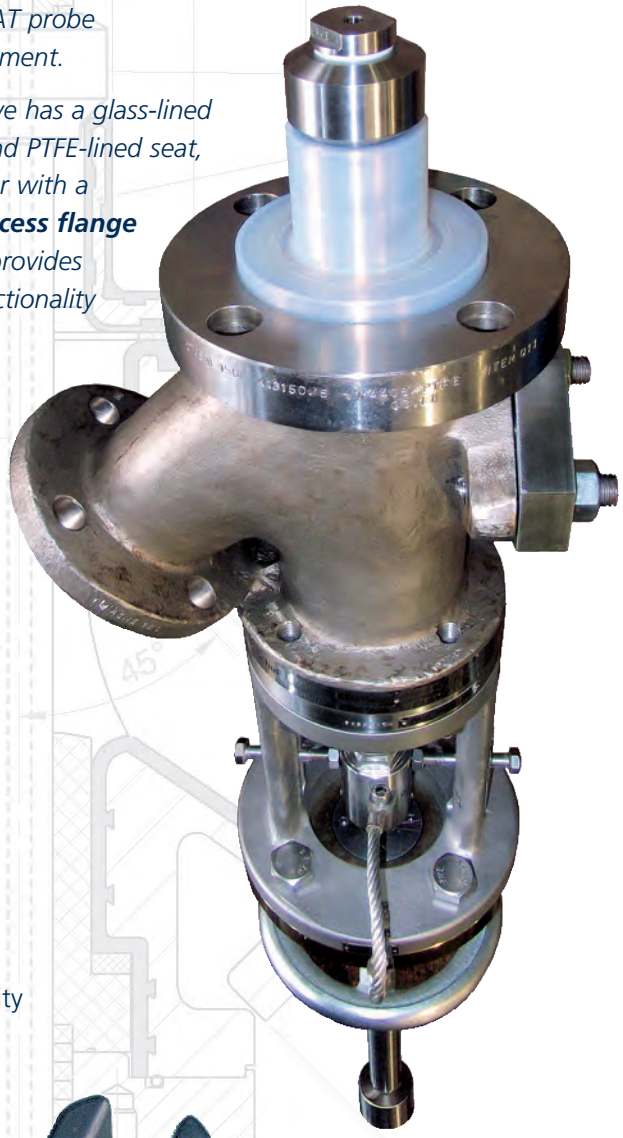
- **FTIR (mid- and near-IR ranges)**
- **RAMAN**
- **Turbidity**
- **ATR**
- **LiquiSonic®**
- **pH**



Above: A SchuF disc-rising drain valve with double-shaft PAT probe and temperature sensor arrangement.

Right: A SchuF disc-rising drain valve with single-shaft PAT probe arrangement.

The valve has a glass-lined body and PTFE-lined seat, together with a ***side-access flange*** *which provides CIP functionality*



Further Sensor Technology

LiquiSonic® from SensoTech:

- Measure absolute sonic velocity in the process liquid
- Detect & monitor liquid concentration and density
- Probe is open to the process (full immersion)
- Integral part of the valve disc

Case Study: SchuF MultiProbe™ Valve- Bespoke PAT Type 25X

Pfizer UK outline how PAT technology can be introduced- even with limited reactor entry points

Staff at Pfizer R&D had introduced online mid-infrared (IR) spectroscopy in the research laboratories as an important tool for understanding and optimising processes on a small scale before upscaling to commercial manufacturing processes. There are significant challenges facing the transition of this technology from the laboratory to larger-scale manufacturing, and perhaps the most significant challenge arises because of the general lack of suitable entry points for the measurement technology into the reactor vessels and the prohibitively high cost of modifying or replacing the reactors in a facility to enable PAT to be used throughout.

Bespoke PAT

To overcome this problem, Pfizer UK utilised a bespoke drain valve configuration with built-in online IR monitoring capability. Figure 1 (below, right) shows the schematic of the drain-valve with integrated IR probe. In this design, an oversized actuator and valve bellows were used to accommodate the extra diameter required for an IR probe. In use, the IR probe protrudes through the valve plug, adjacent to a temperature probe, and performs measurements in the body of the liquid held in a reactor. A specialised two-seal design enables the IR-probe to be retracted for replacement or repair if required. This overall design also provides another layer of flexibility because the probe is a stand-alone unit and can be connected to an online mid-IR instrument or transferred to the laboratory and used with a lab-based instrument. These Hastelloy valves have been designed with two types of bespoke reactor seal, so that they can be used on both Hastelloy and glass-lined reactors of various sizes, eliminating the risk of damaging the glass-lined reactor neck.

Low-cost solution

This relatively low-cost solution has enabled PAT technology to be applied across 22 reactors in the facility without the need to modify any of the equipment – a significant improvement from the three reactors that previously had ports suitable for the IR probes. Although it was previously possible to install an IR probe via a recirculation loop incorporating an IR flow-cell, this arrangement has a number of safety concerns. These include hazards associated with reactive chemistries in flexible hoses: difficulty in recirculation of heavy slurries: and also, this setup is not suitable for temperature-sensitive chemistry. Further advantages offered by the new approach include the fact that we can generate PAT data even at the minimum working volume in a reactor; we are able to monitor cryogenic and high-temperature reactions, and, if required, correct the spectral data for the effect of changing reactor content temperature.

Pic: ©Pfizer UK

Therefore this relatively simple but innovative valve installation has the potential to significantly impact the business through reduced batch cycle time, improved quality and increased process robustness.

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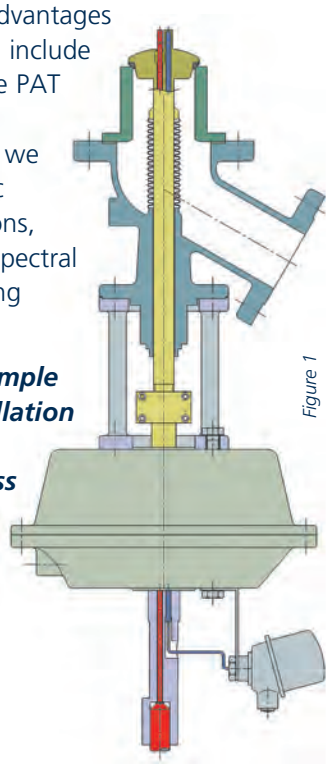

Figure 1

Process Analytical Technology

Case Study: Pharmaceutical valve with PAT & Filtration Function

SchuF valves are tailor-made to match the customer's precise requirements.

As well as operating in its primary function, a SchuF valve can provide additional PAT functionality in a number of areas. There follows is an example of a valve which was designed with such multifunctionality in mind.

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The Roche Group is a leading international healthcare company with principal businesses in pharmaceuticals and diagnostics.

Roche Ireland, based in Clarecastle, Co Clare, is a manufacturing centre of excellence for the production of active pharmaceutical ingredients destined for conversion to medicines in dosage form at other Roche facilities throughout the world.

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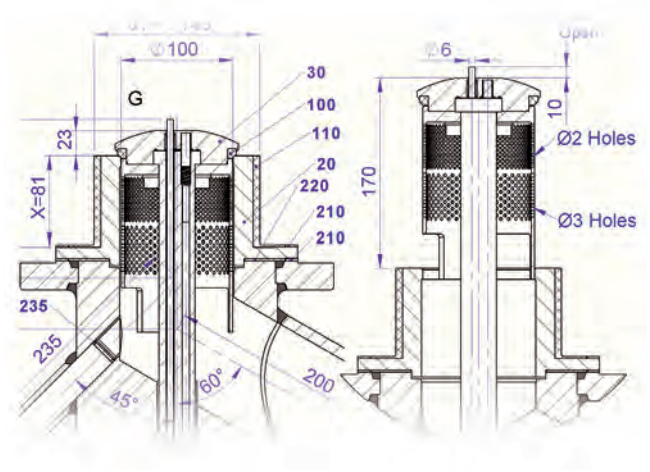
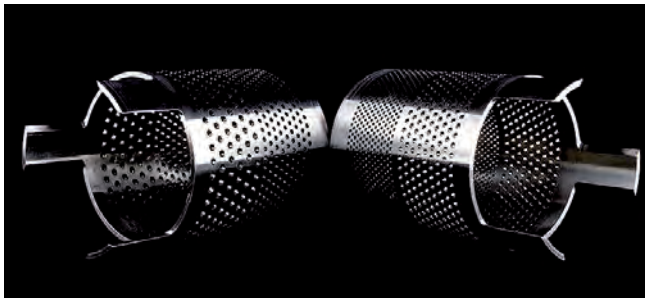


The Process Issue

SchuF have been able to provide a technical solution to a difficult process which had previously been an issue for Roche.

The core activity of this Roche process is one of particle engineering. The product crystallises in the medium as temperature is reduced, and here real-time measurement of the reaction is crucial to the success of the entire process. In addition, extremely fine adjustment of the flow rate from the vessel is required.



Case Study: Pharmaceutical Valve with PAT & Filtration Function

The Solution

- Initially, the valve keeps the vessel 100% closed when the process is initiated.
- The valve provides parallel PAT and temperature-sensing functions. In this particular process, the temperature of the reactor is being reduced to bring about crystallisation of the product. Thus the temperature is continuously monitored while the PAT probe is used to measure turbidity, which will indicate when the optimum conditions for crystallisation have been reached.
- At this point in the reaction, the valve can be opened with an incredibly fine degree of precision due to the pneumatically-operated actuator. This fine control, in conjunction with the integral filter/strainer with its graduated level of particulate straining, allows the carefully-controlled releasing of the solvent liquors.
- This finely-adjusted flow rate allows the crystallising product to physically support itself in the reactor, allowing the solvent to drain through while creating the opportunity for the desired larger-sized crystals to form as the de- liquoring process continues.
- Dr. John O'Reilly explained that a normal valve would not have been acceptable for their needs. He goes on: "The resulting design is one which provides a solution which could otherwise only have been achieved by potentially spending millions on a full Hastelloy separation system".
- The conventional process, which would include a set of reactors and separators, plus the transferring of material between processes (the reaction would take place in one vessel, crystallisation in another) and the various cleaning and preparation steps, could require a number of days to reach completion. Utilising the SchuF valve allows the operation to be done in 30 minutes, with minimal effort and increased control.

SchuF, in conjunction with Senior Analytical Chemist Dr. John O' Reilly and Roche technical staff, was able to provide a Drain Valve which incorporated a number of crucial capabilities.

Customer Enquiry Sheet

Part 1 – Your Company Information

Name: Title:

Company: Telephone:

E-mail: Fax:

Part 2 – Your Order Information

General:

Quantity: Application:

Tag No.: Project Name:

Valve Model: Project No.:

Part 3 – Valve and Process Information

Valve Information:

Valve Inlet Size (DN/Inch): Valve Pressure Rating:

Valve Outlet Size (DN/Inch): Valve Delta P:

Inlet Flanged/Weld-End: Outlet Flanged/Weld-End:

Operating Temp.: Operating Pressure:

Design Temp.: Design Pressure:

Body Material: Trim Material:

Medium: Fugitive Emissions/Clean Air:

Certificates Etc.: Firesafe Rating:

Actuator Type: Air Supply Pressure:

Air-Fail Position: Manual Override:

Part 4 – Further Notes/Topics/Info

Product Portfolio Overview

The SchuF Group has delivered over one million valves during its 100 year history to a wide variety of industries in over 50 countries worldwide.

Headquartered near Frankfurt in Germany, the company has additional design and manufacturing centres in Italy, India, Ireland, UK and the USA.

The SchuF Group has sales and agent offices covering almost every country in the world.

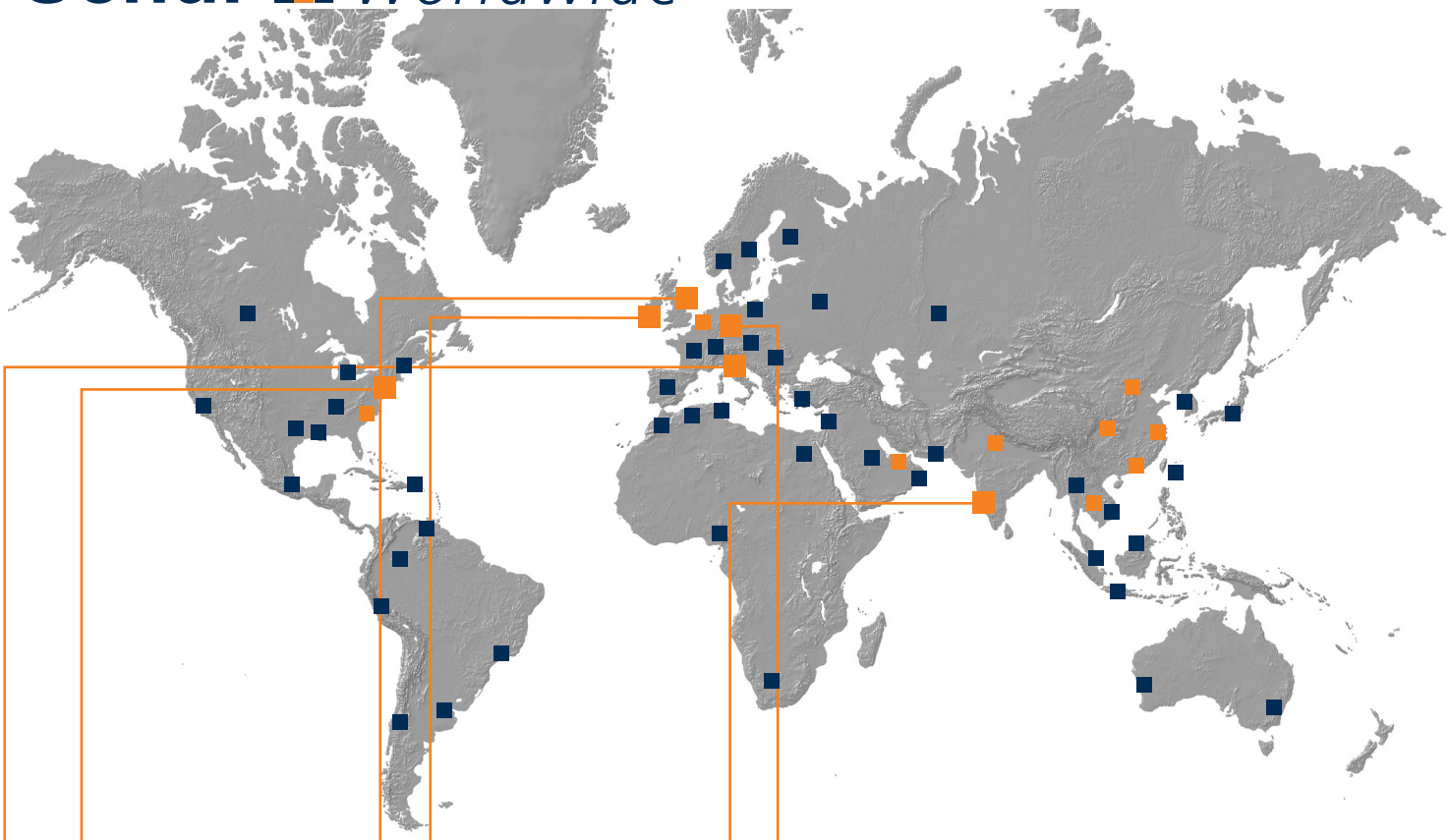
We manufacture valve products that control, isolate, divert, and sample liquids, gases, powders, and slurries. Our product range of engineered, customised valves includes:

Drain & Sampling Valves	Isolation Valves	Control Valves	Switching Valves	Spray Rinse & Injection Valves	Safety Related Valves
Piston Bottom Outlet Valves	Lift Plug Valves	Angle Control Valves	Y, R & T type Diverter Valves	Spray Rinse Valve	Line Blind Systems
Disc Lowering / Rising Bottom Outlet Valves	TruEPlug Valve	Multistage Control Valves	Multiway Diverter Valves	Steam Injection Valve	Changeover Valves
Custom Bottom Outlet Valves	Globe Valves	Cage Control Valves	SwitchPlug Valve		Emergency Tank Shut-off Valves (TESO)
Screw-in, Line & Wafer Sampling Valves	High Pressure Angle Valve	In-line Control Valves	ManiFlow Selector Valve		Customised Valves
	Special Gate Valves	Automatic Recirculation Valves	Custom Diverter Valves		

Pharma Valves Client List:

- Abbott
- AbbVie
- Amgen
- Astellas Pharma
- AstraZeneca
- BASF
- Bayer
- BMS
- Boehringer Ingelheim
- Bristol-Myers Squibb
- CAD Middle East
- Dow Chemical
- DSM
- Eisai Co
- Eli Lilly
- GE Healthcare
- GlaxoSmithKline
- Hospira
- Janssen
- Johnson and Johnson
- Lonza
- Merck
- Monsanto
- Novartis
- Pfizer
- Roche
- Sanofi
- Scinopharm
- Shasun
- Syngenta
- Takeda
- UCB

SchuF Worldwide



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