



ChargePoint 
PharmaSafe[®]

POWDER TRANSFER
CONTAINMENT VALVES

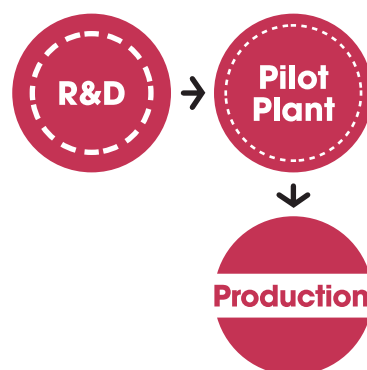
ChargePoint PharmaSafe®

- Ensure **industry regulatory compliance**.
- Process toxic powders, ensuring the **safety of your personnel** and a **dust free environment**.
- **Reduce risk of cross contamination** with closed transfers that limit manual intervention.
- Meet **GMP and product quality** requirements.
- **Maximize yield** transferring poorly flowing and high value product.
- Remove requirement for high air class control areas and cumbersome PPE.

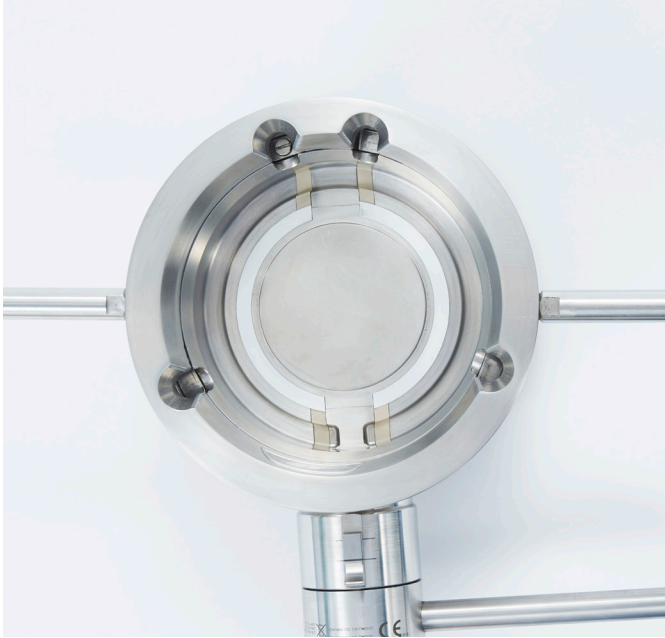
Applications

Contained filling and emptying for all production processes.

Processes		Ingredients	Materials
Dispensing	Blending / Mixing	API	Powder
Vessel Charging	Milling	Reagents	Semi-solid
Filtration / Separation	Sieving	Intermediates	Granular
Centrifugation	Compression	Excipients	Suspension
Drying	Filling	Formulated blends	Tablets / Capsules
Sampling	Coating	Raw materials	Liquid
Mixing			
Wet/Dry Granulation			

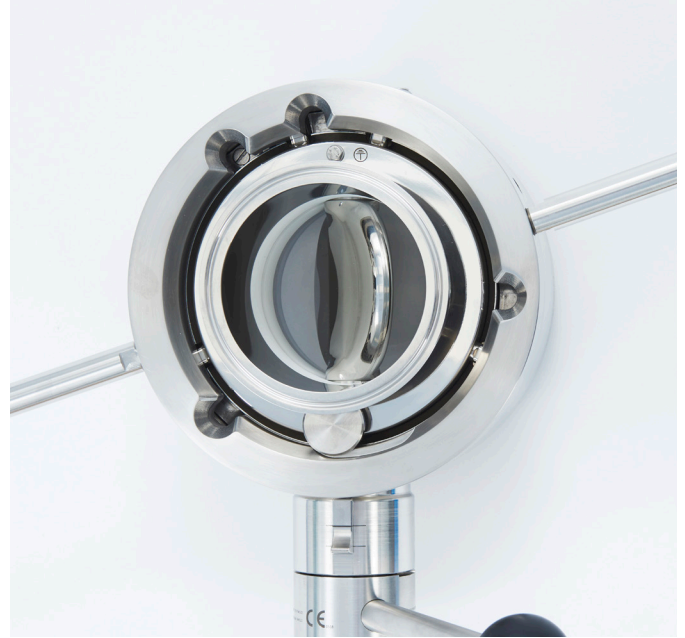


Features & Benefits



Optimised Seal Design

Precision tolerance interchangeable seat design for low wear, easy operation and repeatable performance.



Metal-to-Metal Disc Seal

Simple GMP design without additional disc-to-disc sealing ensure reduced risk of compromise and easier maintenance.



Safety Interlocks

Safety for personnel and process with mechanical interlocks and optional electro/pneumatic control integration.



Process Versatility

In addition to charging and dispensing ChargePoint can accommodate functions such as WIP/CIP, COP, sampling and process inspection (sightglass).

Validated Performance

Independently validated according to ISPE SMEPAC guidelines 4 performance iterations are available to meet product potency down to nanogram Levels.

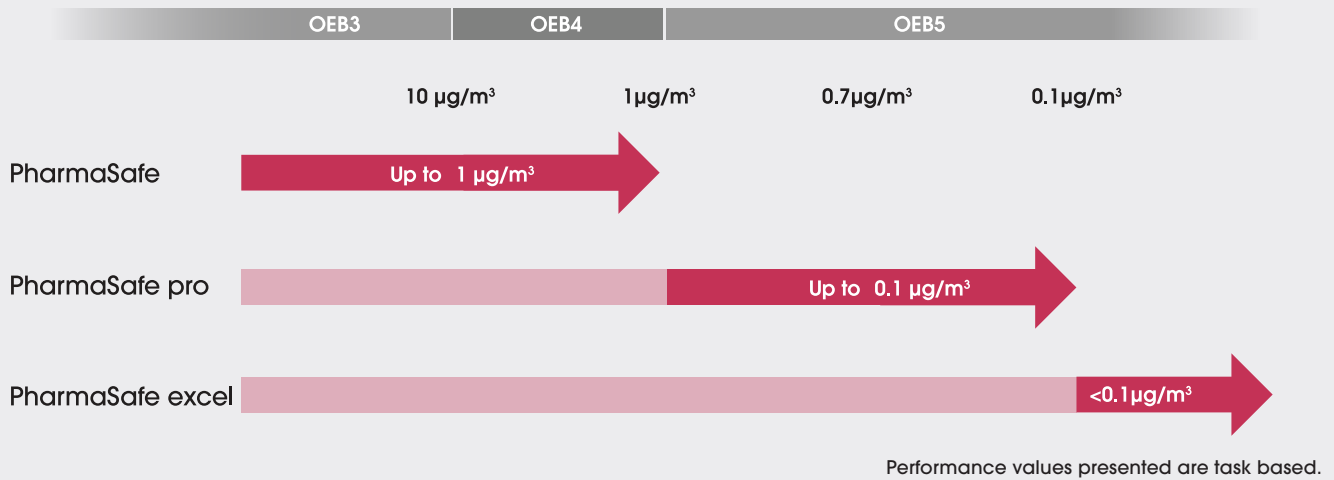
Secure Pressure/Vacuum Rating

A unique method of achieving a seal allows for transfers under pressure/vacuum with additional benefits for powder flow, reduction in seal wear and ease of operation compared to other systems.

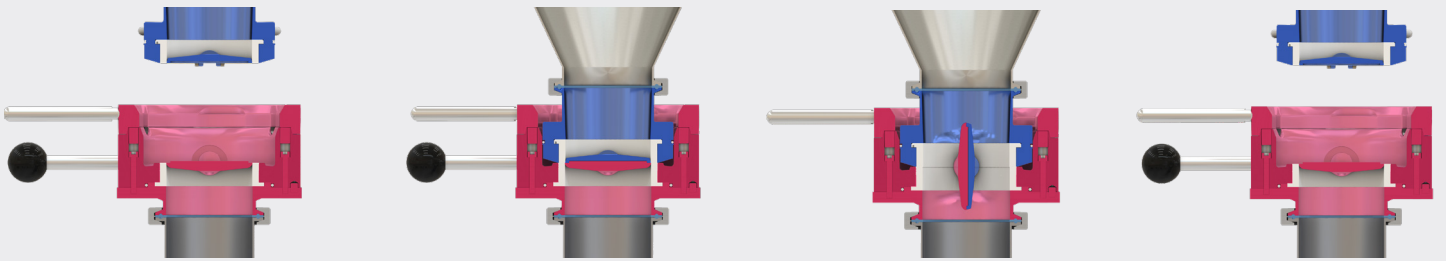
Containment Performance



ChargePoint PharmaSafe® valve containment performance has been independently validated by customers and 3rd parties according to the ISPE SMEPAC (Standardised Measurement of Equipment Particulate Airborne Contamination) guideline.



Operation Sequence



1 The Active and Passive units are docked together. Each half of the valve consists of one half of the butterfly valve disc. Each unit is sealed and cannot be opened unless they are docked together.

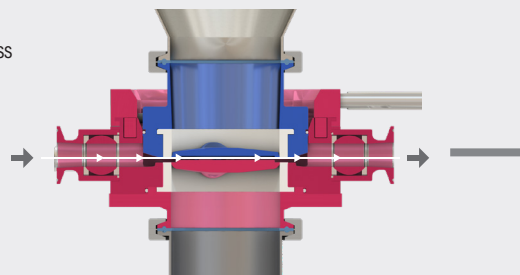
2 Two disc halves are locked in place to form a single sealed unit. The previously exposed interfaces are now sealed together to form a single butterfly valve disc.

3 The Active unit is the driving half of the valve. Once operated the disc will open to allow the transfer of material through the valve. The active and Passive interface is sealed to ensure no material can penetrate the critical area. Once the transfer has taken place the valve is closed.

4 The Active and Passive units are then unlocked and undocked revealing the previously closed interfaces ensuring a dust free transfer.

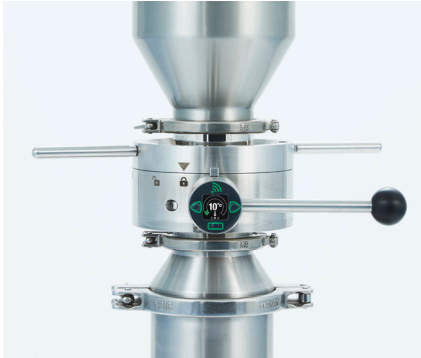
A Optional Extraction Process

Optional higher performance extraction process on PharmaSafe® pro and excel.



Product Range

Up to $1\mu\text{g}/\text{m}^3$ / OEB4



ChargePoint PharmaSafe®

High containment performance with no additional seals, vacuum or extraction required.

The entry level ChargePoint PharmaSafe® offers a simple, cost effective upgrade to facilitate the required GMP and containment requirements in manufacturing. The minimum part design is easy to operate, clean and maintain whilst providing outstanding entry level performance.



Up to $0.1\mu\text{g}/\text{m}^3$ / OEB5



ChargePoint PharmaSafe® pro

High containment performance with a simple, low volume extraction.

The PharmaSafe® pro utilises an extraction process which is integral to the valve, to minimise the volume of airborne contamination during the valve undocking sequence. The extraction requirement is specified to be compatible with most existing onsite handling systems.



$<0.1\mu\text{g}/\text{m}^3$ / OEB5



ChargePoint PharmaSafe® excel

Advanced performance to low nanogram levels in a compact efficient split valve.

The ChargePoint PharmaSafe® excel incorporates purge and extract connections on the Active Unit. During the undocking step a sealed gap is created between the Active and Passive interface. A purge and extraction process is run to remove traces of particles that can potentially become airborne once the valve is fully undocked.



Specifications

		PS50	PS100	PS150	PS200	PS250
ChargePoint PharmaSafe®	Up to 1 µg/m ³	•	•	•	•	•
ChargePoint PharmaSafe® pro	Up to 0.1 µg/m ³	•	•	•	•	•
ChargePoint PharmaSafe® excel	< 0.1 µg/m ³		•	•	•	
Size		DN50 (2")	DN100 (4")	DN150 (6")	DN200 (8")	DN250 (10")
Pressure Rating*		Up to 6 Bar (87psi) Option for 10 Bar (145 psi)		Up to 6 Bar (87psi)	Up to 3.5 Bar (50 psi)	None
Vacuum Rating*		Full vacuum				•
Operation	Manual	•	•	•	•	
	Semi Automatic		•	•	•	
	Fully Automatic		•	•	•	•
Product Contact Material	Body					
	316L	•	•	•	•	•
	Alloy 22	•	•	•	•	•
	POM (Passive only)		•	•	•	
	Seals					
	EPDM	•	•	•	•	•
	FKM	•	•	•	•	•
	FFKM	•	•	•	•	•
Connection Interface	Tri-Clamp (BS/ISO/DIN/JIS)	•	•	•	•	•
	PN6/10/16	•	•	•	•	•
	ANSI	•	•	•	•	•
	Other	Available to suite process / container				

*Pressure/vacuum Rated only when fitted with a suitable pressure/vacuum rated component or accessory

Compliance & Quality Assurance

- ✓ Designed to GMP standards
- ✓ FDA compliant materials
- ✓ Conforms to European Hazardous Area directive (ATEX)
- ✓ Conforms to European Pressure Equipment Directive (PED)
- ✓ European Machinery Directive
- ✓ Manufactured in ISO9001 accredited facilities
- ✓ Full material certification and batch traceability
- ✓ Independently validated according to ISPE containment performance measurement (SMEPAC) guidelines

Air Handling Control Systems

ChargePoint supply a range of dedicated air handling and control systems that provide safe dust particulate extraction in conjunction with the PharmaSafe® plus and excel containment valves.

- HEPA Filtration with simple safe change.
- Mobile units for use across multiple installations.
- Simple pneumatic or advanced PLC based controls with integrated valve controls and sequence timings.



Cleaning & Washing

The ability to effectively clean or wash the product contact and sealing areas of a ChargePoint® valve is assured with the use of our specifically designed Wash In Place (WIP) devices.

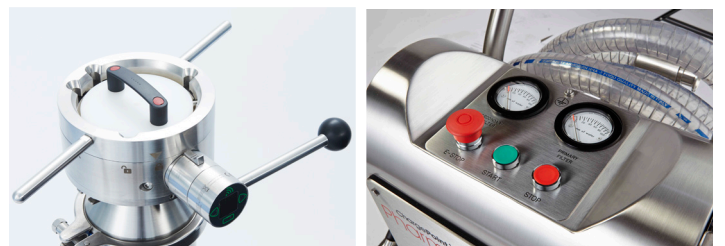
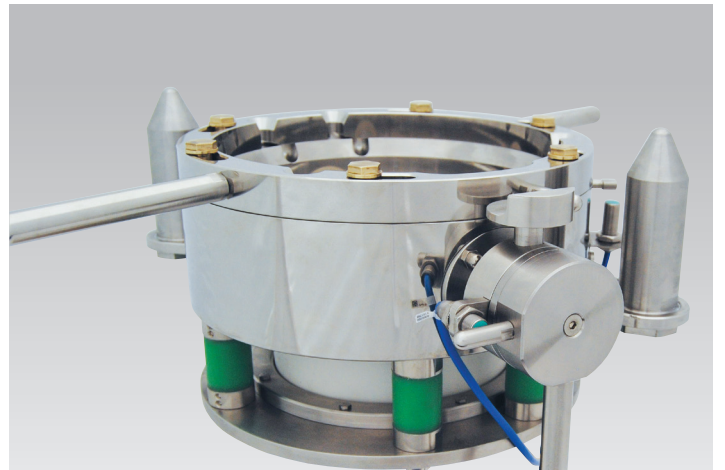
- Suitable for cleaning within an autoclave.
- GMP design specifically considered for effective cleaning.
- Local WIP of the Active valve product contact and sealing surfaces in place.
- Remote WIP of the Passive valve and connected containers including IBC wash stations.
- ATEX rated designs.



Handling & Automation

Systems to ensure safe operation in hazardous or inaccessible areas or where the production scale does not permit manual handling:

- Manual or automated valve operation and docking.
- Proximity sensors
- Control systems
- Repeatable and safe alignment of equipment in conjunction with lifting hoists and docking systems.
- Reduced weight versions.
- GMP covers to protect the valve while not in use.



ChargeBag®



ChargeBag® PE-S | PE-SBV

- ChargeBag® is a cost effective and convenient single use container for the handling, storage and transfer of bio-pharmaceutical powders.
- Manufactured from HiPure ULP7, a proprietary LLDPE film from ChargePoint Technology, with extremely high levels of integrity with optimised purity.
- The statically dissipative film means ChargeBag® is also suited for use in hazardous areas.
- 100% pressure tested to verify the integrity of each bag.
- Cleanroom manufactured for high levels of quality control.



ChargeBottle®



ChargeBottle® P | P2

- 0.5L to 20L robust powder transfer containers.
- FDA compliant, Polypropylene and HDPE construction options.
- Maximise product flow and yield with optional flush port (10/20L only)

ChargeBottle® M | MX

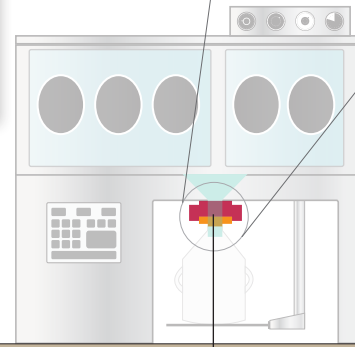
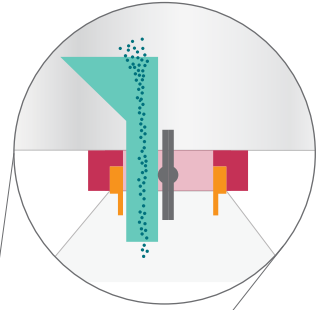
- 1L to 20L Stainless steel containers with optional pressure rating.
- Maximise flow and yield with optional wet/dry purge port.
- Optional sightglass viewing ports.



Manufacture of API's and Intermediates

Secure Vessel Charging

- Pressure/vacuum retention up to 10bar (145psi)
- Sightglass accessories
- Valve can be open under pressure conditions for wet/dry assisted product flushing
- Washing devices available
- High temperature and chemical resistance



Powder Dispensing

- Funnels can be utilised to improve containment results
- Weight isolation designs available



Dryer discharge

- Filter / Dryer discharge into IBC's, bottles or bags

Dust free milling / sieving

- Contained charge and discharging with optional pressure retention design for nitrogen inertion



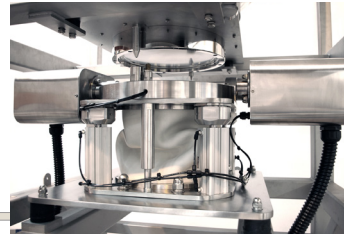
High containment secondary pharmaceutical manufacturing

Common interface from dispensing through to compression / filling

Key:  Passive
 Active

Dispensing

- Weight isolation available for integration with weighing systems.



Washing In Place (WIP)

- WIP Passive devices can be installed in the upright or inverted orientation
- Washing media can be inserted via the WIP Passive device or from the process



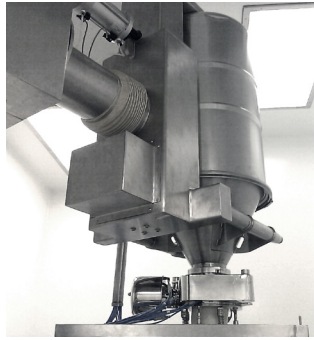
Repeatable docking accuracy

- PowerDock - automated raise and lower docking corrects lateral misalignment to ensure repeatable performance
- Assisted manual raise and lower docking versions available



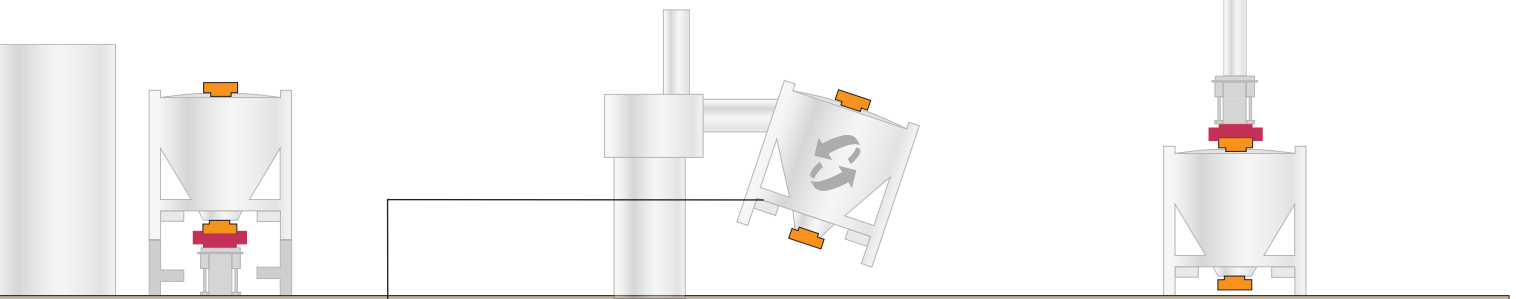
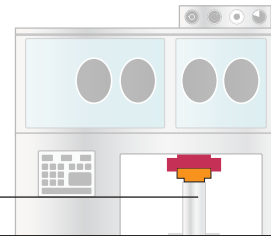
Manual or Automatic Versions

- Even larger PharmaSafe® valves can be operated manually.
- Maintain simple and easy handling processes.



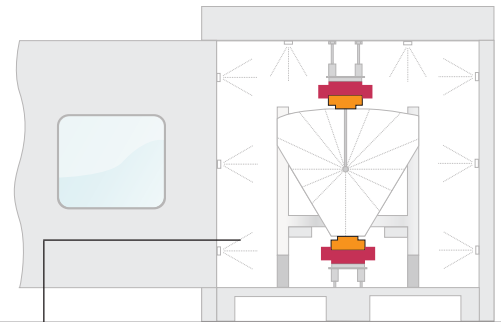
Powder Dispensing

- Higher containment performance systems can be utilised prior to ingredient dilution without need for different Passive designs.



Safe IBC Blending / Mixing

- Passive valve safety interlock
- Additional Passive cover provides assurance
- Pressure rated versions available



Trouble free docking with hoist systems

- Smooth integration with hoist systems can be assured with the use of a compensator device to accommodate and absorb the forces generated during docking processes.



Effective IBC Washing

- Wash Active valve can be integrated into IBC wash stations
- Specifically designed to optimise results.
- This valve can be used in high temperature and ATEX rated environments.





Assisting you throughout the warranty period and continuing to offer our responsive support to ensure continuity of production with Onsite Service Packages, Spare Parts, Consumables and Training delivered via our dedicated support centres in Europe, North America and Asia.



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