

# ChargePoint PharmaSafe<sup>®</sup>



## POWDER TRANSFER CONTAINMENT VALVES

- Safer handling of highly potent API and formulation ingredients
- Nanogram level containment performance
- R&D to pilot and production scale formulation

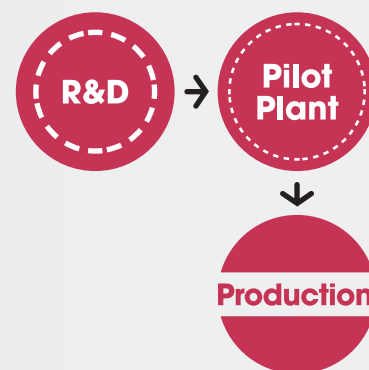
# ChargePoint PharmaSafe®

- Ensure **industry regulatory compliance**.
- Process highly potent ingredients (HPAPI), ensuring the **safety of your personnel** and **reduced environmental contamination**.
- **Reduce risk of cross contamination**.
- Meet **GMP and product quality** requirements.
- **Maximize yield** transferring poorly flowing and high value product.
- **Facilitate respirator free and 'shirt-sleeve' manufacturing initiatives** by removing costly secondary barrier containment and cumbersome PPE.

## Applications

Contained handling for all production processes.

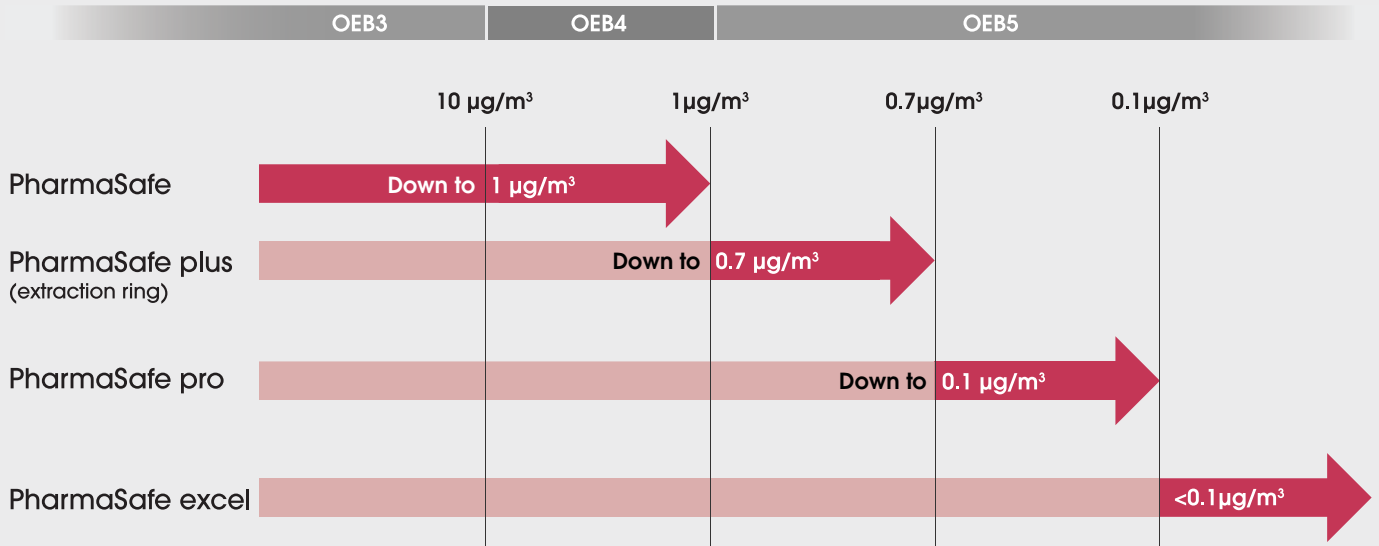
Processes		Ingredients	Materials
Dispensing	Blending	HPAPI	Powder
Vessel Charging	Milling	Reagents	Semi-solid
Filtration	Sieving	Intermediates	Granular
Centrifugation	Compression	Excipients	Suspension
Drying	Filling	Formulated blends	Tablets / Capsules
Sampling	Coating	Raw materials	Liquid
Granulation			



## Containment Performance



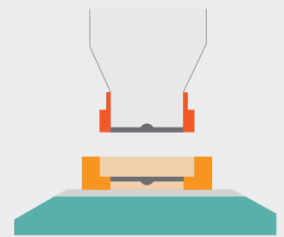
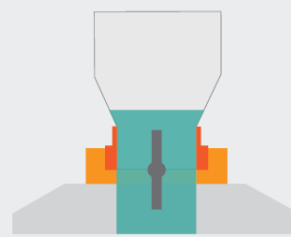
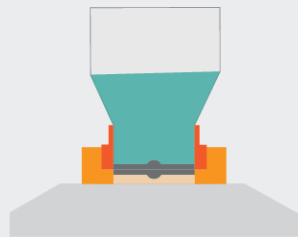
ChargePoint PharmaSafe® valve containment performance has been independently validated by customers and 3<sup>rd</sup> parties according to the ISPE SMEPAC (Standardised Measurement of Equipment Particulate Airborne Contamination) guideline.



Performance values presented are task based.

## Operation Sequence

**A** Optional Extraction Process



**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, whilst minimising the level of dust exposure.

**A** Optional higher performance extraction process on PharmaSafe plus, pro and excel.

## Product Range

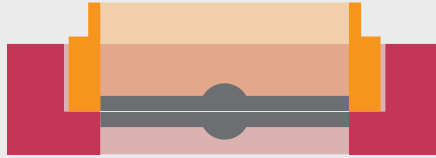
Down to  $1\mu\text{g}/\text{m}^3$  / OEB4



### 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.



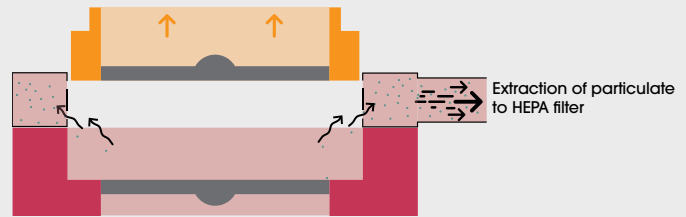
Down to  $0.7\mu\text{g}/\text{m}^3$  / OEB5



### ChargePoint PharmaSafe® plus

An economic upgrade to higher performance. Can be used as a retrofit to existing installations or as a modular unit in facilities with multiple ChargePoint® valves.

The ChargePoint PharmaSafe® plus extraction ring couples to the active unit and is connected to an extraction source. High volume extraction during undocking ensures that airborne particulates are safely captured in the extracted air stream.



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



### ChargePoint PharmaSafe® pro

High containment performance with a simple, low volume extraction.

The ChargePoint PharmaSafe® pro utilizes an extraction process which is integral to the valve, to minimize the level of airborne contamination during the valve undocking sequence. The extraction requirement is designed to be adaptable with existing onsite air handling systems.



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



### ChargePoint PharmaSafe® excel

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

The ChargePoint PharmaSafe® excel incorporates a simultaneous purge and extract sequence. During the undocking step a sealed cavity is created between the Active and Passive interface. The purge and extraction process is synchronized to remove traces of particles that can potentially become airborne once the valve is fully undocked.



## Features & Benefits

### Optimum seat design

Each ChargePoint® seat is manufactured within a precise tolerance to ensure an optimum level of performance:

- Repeatable performance over lifetime of equipment.
- Guaranteed interchangeability of seats between Active and Passive units.
- Easy manual operation even with larger valve diameters.
- Dimensional consistency of replacement seats.

### Metal to metal disc seal

No additional solid or inflatable seals ensure a simple GMP design:

- Reduced risk of damage that could compromise containment integrity.
- Minimal parts for easier and lower cost maintenance.
- Reduced need to remove additional seals to be assured of decontamination.

### Single body design

A single piece robust design with minimal parts:

- Easier maintenance.
- Longer lifetime trouble free performance.
- Passive seat can be removed manually in seconds.

### Secure pressure / vacuum rated design

A unique method of achieving a pressure seal:

- Powder transfer can be achieved with pressure or vacuum assistance.
- Active disc retains low profile thickness, thus maximizing flow, whilst also minimizing disc-seat friction and consequential wear.
- Design enables easy manual operation of even larger valve diameters.

### Safety Interlocks

Safety for the process and personnel:

- The Active and Passive units cannot be accidentally opened when they are not docked together.
- The Passive unit cannot be removed from the Active unit when the valve is open.
- Additional automated security interlock can be provided.

### Process Versatility

Can be utilized for multiple process functions :

- Product charging / dispensing.
- WIP / CIP.
- Sampling.
- Process inspection (Sightglass).

### Small Footprint

The ChargePoint® valve retains a compact footprint throughout the size ranges with no need for an extended handle to operate the valve manually.

## 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 containment performance measurement (ISPE SMEPAC) guidelines

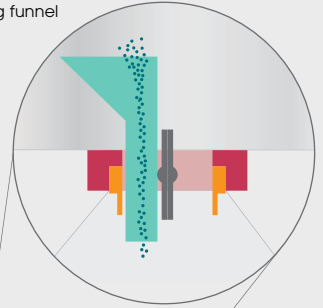
# Manufacture of API's and Intermediates

## Secure vessel charging

- Pressure/vacuum resistant designs up to 10bar (145psi).
- Sightglass accessories.
- In the open position the valve will maintain pressure or vacuum conditions. This allows for dry or wet flushing of IBC's aiding product transfer and optimizing yield.
- High temperature and chemical resistance.



Cross-section of dispensing funnel



## Powder dispensing

- Modular weigh stations with integrated docking, offering weight verification during dispensing operations.
- The use of a Dispensing Funnel within the isolator will improve containment performance of the valve and will minimise product loss during transfer.



## Dryer discharge

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

## Contained milling / sieving

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




# High containment secondary pharmaceutical manufacturing

Common interface from dispensing through to compression / filling




### Dispensing

- Automated docking with weight isolation technology delivers an accurate method of batch weighing



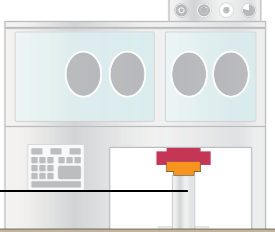
### Manual or automatic Versions

- Wherever possible the ChargePoint design offers the option of manual operation or partial automation versus full automation, reducing the cost and complexity of control systems.
- Larger diameter PharmaSafe valves can also be operated manually.



### Active ingredient dispensing

- When considering API dilution within the formulation blend, higher performance PharmaSafe valves can be used in the same process line as the entry level models without concerns over interchangeability of Passive valves.



### Washing In Place (WIP)

- The Wash Passive devices are designed to offer contained Wash In Place via the Active valve, as well as drain recovery in the inverted orientation.
- Some designs can also be pressure rated, accommodating recirculation, flood or high pressure washing cycles.






### Safe IBC blending / mixing

- Passive valve safety interlock.
- Additional Passive cover provides assurance.





### Repeatable docking accuracy

- PowerDock - automated raise and lower docking also corrects lateral misalignment to ensure repeatable performance.
- Assisted manual raise and lower docking can be used where access permits, offering a cost effective docking solution.

### Trouble free docking with hoist systems

- Compensator devices will accommodate docking forces and specified misalignment when mechanical hoist systems are being employed to raise and lower IBC's.

### Effective IBC washing

- Fully automated Wash Active valve can be incorporated into IBC Wash stations.
- Specifically designed to optimise decontamination results and operate within high temperature environments.



## Specifications

		PS50	PS100	PS150	PS200	PS250	PS300	
<b>PharmaSafe</b>	Down to 1 µg/m <sup>3</sup>	•	•	•	•	•	•	
<b>PharmaSafe plus</b>	Down to 0.7 µg/m <sup>3</sup>	•	•	•	•			
<b>PharmaSafe pro</b>	Down to 0.1 µg/m <sup>3</sup>	•	•	•	•			
<b>PharmaSafe excel</b>	<0.1 µg/m <sup>3</sup>	•	•	•	•			
<b>Size</b>		DN50 (2")	DN100 (4")	DN150 (6")	DN200 (8")	DN250 (10")	DN300 (12")	
<b>Pressure Rating*</b>		Up to 6 Bar (87psi) Option for 10 Bar (145 psi)		Up to 6 Bar (87psi)	Up to 3.5 Bar (50 psi)	None		
<b>Vacuum Rating*</b>		Full vacuum						
<b>Operation</b>	<b>Manual</b>	•	•	•	•	•	•	
	<b>Semi Automatic</b>		•	•	•			
	<b>Fully Automatic</b>		•	•	•	•	•	
<b>Product Contact Material</b>	<b>316L</b>	•	•	•	•	•	•	
	<b>Body Alloy 22</b>	•	•	•	•	•	•	
	<b>POM (Passive only)</b>		•	•				
	<b>EPDM</b>	•	•	•	•	•	•	
	<b>Seals</b>	<b>FKM</b>	•	•	•	•	•	•
		<b>FFKM</b>	•	•	•	•	•	•
<b>Connection Interface</b>	<b>Tri-Clamp (BS/ISO/DIN/JIS)</b>	•	•	•	•	•	•	
	<b>PN6/10/16</b>	•	•	•	•	•	•	
	<b>ANSI</b>	•	•	•	•	•	•	
	<b>Other</b>	Available to suite process / container						

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

## 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:

- Static or penetrative type WIP devices.
- Static WIP Passive offers elementary local decontamination.
- Penetrative WIP Lance offers high level cleaning.
- WIP Lance arrangement incorporated within Bottle Wash Stations.
- WIP Active valve allows cleaning of Passive and connected IBC's within remote 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:

- Fully or partially automated versions can be provided to suit application.
- Status information and sequence interlocking, secured with the use of pneumatic or electric proximity sensors.
- Fully integrated and factory tested 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.



**Also available - our range of high integrity single use transfer bags and robust containers.**

ChargeBag® & ChargeBottle®





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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