



TEST REPORT

Independent Containment Performance Testing of a ChargePoint® Split Butterfly Valve

March 2010

INTRODUCTION

ChargePoint split butterfly valves are designed to minimise the presence of potentially hazardous airborne particles during powder transfer operations within pharmaceutical manufacturing processes.

The industry has quantified the potential risk to the operating staff when handling these potent products. This measure is known as the product OEL 'Occupational Exposure Limit' which is defined as the maximum allowable exposure over a given period of time and is expressed in $\mu\text{g}/\text{m}^3$ (micrograms per cubic meter).

Split butterfly valve technology is one of various forms of 'containment' equipment that offer a solution to the protection of operators, fundamentally selected as a result of the required OEL of the product being handled. A typical split valve will achieve a containment performance of $1\text{-}10\mu\text{g}/\text{m}^3$, with more advanced systems, involving extraction, achieving even higher levels of performance.

In order to validate the performance of a split butterfly valve against the containment criteria, it has been necessary to perform surrogate powder transfer testing. The recommended procedure for containment performance testing is outlined in the ISPE Good Practice Guide, 'Assessing the Particulate Containment Performance of Pharmaceutical Equipment' which was developed by the SMEPAC (Standardised Measurement of Equipment Particulate Airborne Concentration) Committee.

The guide covers the main factors that affect test results for specific contained solids handling systems, including material handled, room environment, air quality, ventilation and operator technique all based upon best practice within the industry.

METHODOLOGY

Test Date 25th March 2010

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Test Location ChargePoint Technology
80 Venture Point West
Evans Road
Liverpool, L24 9PB

Test Containment Equipment **100mm ChargePoint® - Split Butterfly Valve**
Non Pressure Rated, 316L Body, EPDM Seats and O-Rings.

25L ChargeBag



Test Procedure

In line with the ISPE Good Practice Guide, 'Assessing the Particulate Containment Performance of Pharmaceutical Equipment' which was developed by the SMEPAC (Standardised Measurement of Equipment Particulate Airborne Concentration) Committee.

Surrogate Powder

Lactose

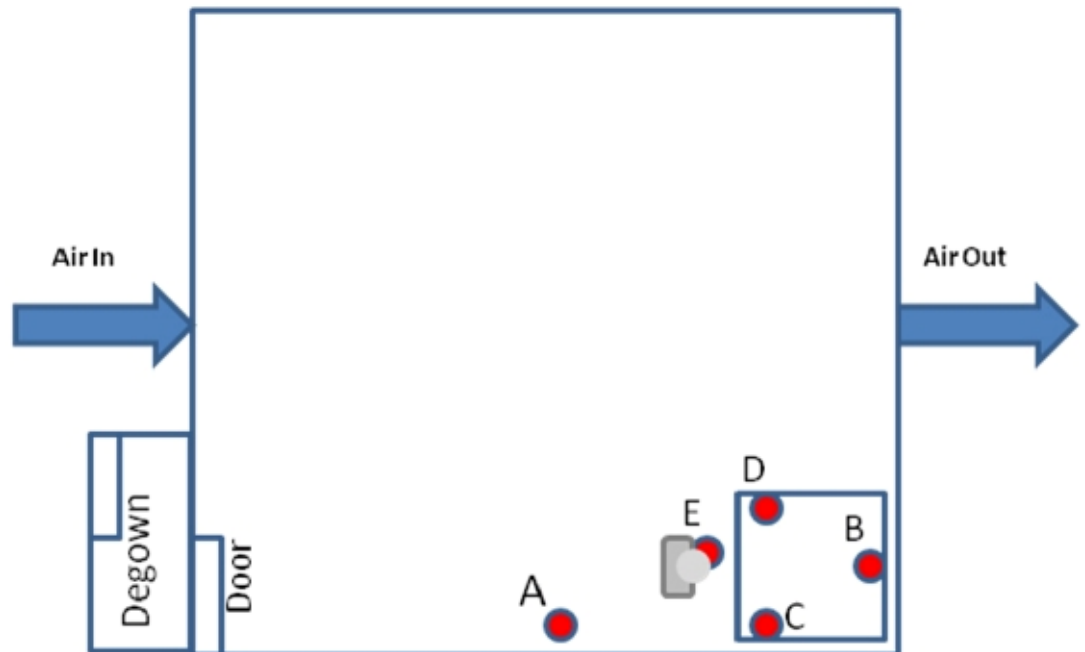
Product Category	Crystalline, milled. Granulac® 230+
Typical Bulk Density (g/cc)	0.45
Particle Size Specification	NLT 90% <63 microns

Test Enclosure

Air Exchange:	4 times per hour
Temperature range:	20°C (+/- 5°C)
Air quality:	Input air supplied through HEPA filter
Air pressure:	+10Pa (slight positive pressure)
Relative humidity:	50% (+/- 10%)



Sample Locations



A - Background

B - Downstream

C - 120 degrees clockwise from B

D - 120 degrees anti-clockwise from B

E - Personal monitor (300mm from nose to mouth)

Sample timing

1 x Static sample prior to assessment

1 x Static sample during assessment

3 x Samples 200mm from the valve

1 x Sample worn by operator

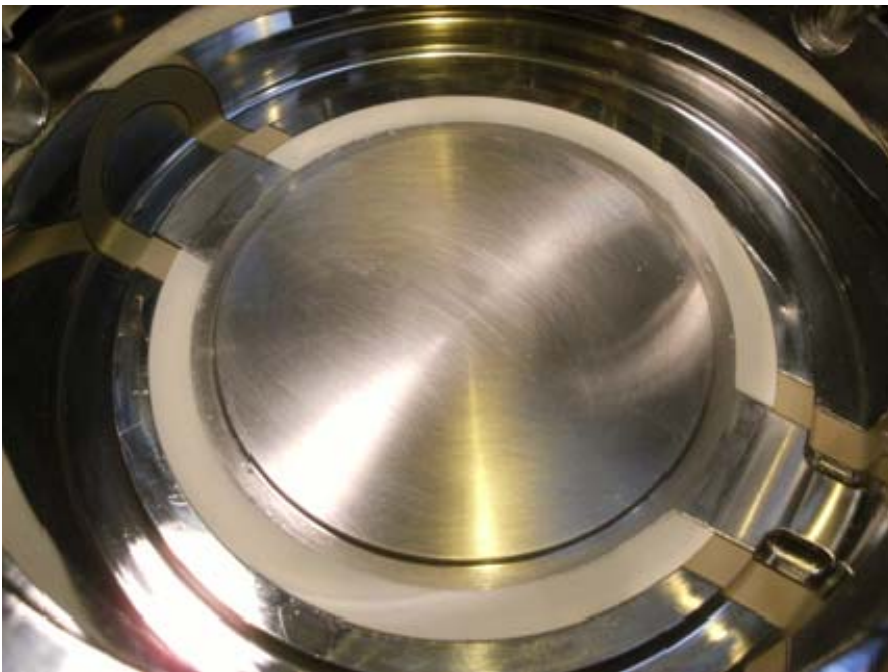
Test Schedule

Containment target ($\mu\text{g}/\text{m}^3$)	Powder weight per operation (kg)	No. of transfers	Test Day
5	4	3	25/03/10

RESULTS

Airborne concentration of lactose ($\mu\text{g}/\text{m}^3$)

	Run 1	Run 2	Run 3
Location A - Background exposure	0.23 $\mu\text{g}/\text{m}^3$	<0.06 $\mu\text{g}/\text{m}^3$	<0.05 $\mu\text{g}/\text{m}^3$
Location B - Downstream	0.13 $\mu\text{g}/\text{m}^3$	0.21 $\mu\text{g}/\text{m}^3$	0.16 $\mu\text{g}/\text{m}^3$
Location C - 120 degrees clockwise from B	0.10 $\mu\text{g}/\text{m}^3$	0.11 $\mu\text{g}/\text{m}^3$	<0.05 $\mu\text{g}/\text{m}^3$
Location D - 120 degrees anti-clockwise form B	0.24 $\mu\text{g}/\text{m}^3$	0.24 $\mu\text{g}/\text{m}^3$	<0.05 $\mu\text{g}/\text{m}^3$
Location E - Operator exposure	0.39 $\mu\text{g}/\text{m}^3$	0.68 $\mu\text{g}/\text{m}^3$	<0.05 $\mu\text{g}/\text{m}^3$



ChargePoint Active (post transfer)

This ChargePoint valve performed within our containment performance target of 5 $\mu\text{g}/\text{m}^3$.

These are very reassuring figures and when using Lactose (even with the safety multipliers suggested in European Standard EN 689) the containment performance achieved is well below the target.