Bespoke solution for filling potent compounds using Xcelodose® systems

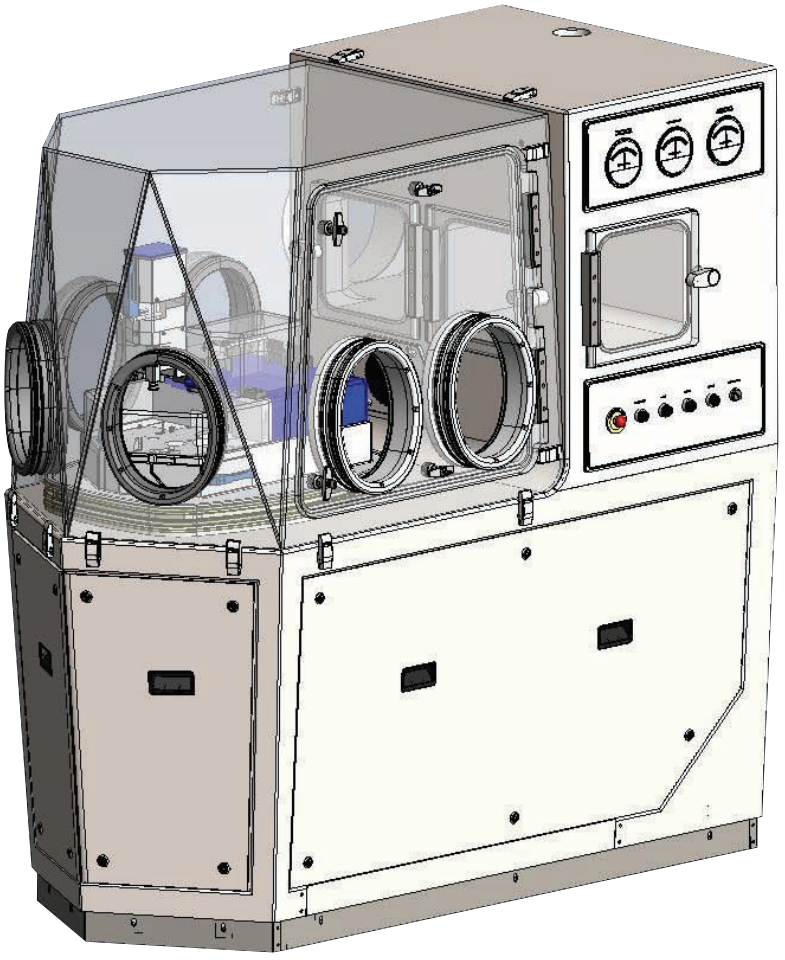
Xceloprotect™ Isolator

The bespoke design of the Xceloprotect isolator meets the needs of the Xcelodose® precision powder micro-dosing systems when filling potent compounds. Containment gives OEL < 1µg per m^3 over an 8 hour time weighted period (the design is intended for Safebridge 3 and 4 applications).

Integration

Integration of the specially modified Xcelodose system, and control cabinet, into the Xceloprotect isolator framework isolates vibration transfer. Existing machines in the field can be retrofitted with a special kit.

All mechanical and electrical mechanisms of the Xcelodose system are contained within the lower half of the isolator to avoid contamination and facilitate easy access without breaking containment. The Xcelodose system deck plate is accessible via the glove ports in the canopy (see 'Ergonomics' on the following page).



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Ergonomics

- Acrylic canopy enables clear visibility for operation from three sides
- Six glove ports allow for ease of access to all areas of the Xcelodose system
- A large and hinged access door facilitates easy clean down and batch change over
- Clean-in-Place (CIP) via the integrated vacuum system incorporating safe change HEPA filtration

Options

- Rapid transfer ports (RTP) (eg: La Calhène, Sartorius, etc.) Interchangeable with bag out port
- Relative humidity control module
- Enhanced control system (tailor made to suit requirements)
- Annual preventative maintenance agreement

Benefits

Financial	
	Reduces wasted product due to cross contamination
	Small footprint frees up lab space for other projects
	Enables facility to work with highly potent products thus increasing product range
	Lower operating and utility cost than a clean room
	Only need to decontaminate and pressurize when in production, unlike clean rooms which have to be maintained all the time
Operator	
	High protection from exposure to potent compounds
	May reduce, or eliminate, the need for gowning and de-gowning
	Easy access for cleaning

Specifications

Containment levels ..... Occupational Exposure Level (OEL) levels < 1µg per m^3 over an 8 hour time weighted period (the design is intended for Safebridge 3 and 4 applications)

Operating pressure ..... Nominally -50 Pa ±10 Pa

Filter specification ..... Stainless steel casing, glass fibre filter, EPT seals, > 99.98% efficiency

Filtration (outlet) ..... Double HEPA Push Push filter using push-push safe change into isolator

Filtration (inlet) ..... Single HEPA Push Push filter

Materials of construction ..... 316 stainless steel structure; 10mm acrylic canopy

Glove ports ..... 300mm high density polyethylene with white ethylene propylene diene Monomer (EPDM) seals

Gloves ..... Thin walled latex gloves with Hypalon sleeves and double O ring safe change cuffs

Bag out port ..... 250mm for use with continuous liner

Air lock ..... Interlocked internal/external doors enabling contained transfer of products into isolator

Control system ..... Safe area variable speed pressure control

Extraction ..... Via centrifugal fan to room or extraction system

Wheels ..... Retractable

Maintenance ..... Performed by Capsugel's dedicated Xcelodose factory support team and PSL Serve

Installation and qualification ..... Performed by Capsugel's dedicated Xcelodose factory support team

Electrical standards ..... CE, UL and JIS approved (others as required)

Dimensions ..... 1,880mm high, 1,890mm wide, 1,060mm deep

Xceloprotect weight ..... Approximately 450 kg

Xcelodose control cabinet ..... 600mm high, 600mm wide, 600mm deep

Xcelodose HMI base ..... 550mm high

Xcelodose weight ..... 90kg and 95kg respectively for Xcelodose 120 S and 600 S systems

Designed in partnership with, and manufactured by, Powder Systems Limited

psl

For further information on the Xceloprotect™ Isolator
email ptg@pfizer.com, call +44 1304 644791 or visit www.capsugel.com

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