

# **Xcelodose® Micro-Dosing Technology**

At PCI, ensuring life-changing medicines reach those who need it most is our highest priority. As a truly integrated global CDMO, we are manufacturing, packaging and supply chain experts, harnessing our experience and expertise to deliver you a seamless solution with the ultimate aim of improving the lives of patients.

#### Xcelodose®

Traditional product development of a formulated solid oral drug for Phase I clinical trials typically involves a range of activities including initial compatibility studies, analytical method development, prototype development, short-term stability, process/formulation refinement, Phase I method validation, and finally, clinical manufacture.

Xcelodose® micro-dosing technology removes the need for initial formulation development and the associated stability testing, enabling PCI to achieve fast times to first-in-human (FIH) studies on behalf of its clients.

The fully programmable system ensures exceptional levels of accuracy and precision whilst minimizing wastage of drug substance. We are proud to offer multiple options of micro-dosing technology, delivering individual client volume requirements.

PCI has further invested in Xcelohood™ and Xceloprotect™ containment technology, further enhancing our contained solutions for the development and manufacturing of highly potent drug products.

#### Features of Xcelodose® Technology

#### **Highly Consistent Dose Accuracy**

- Programmable and precise dispensing of dose weights from 100 micrograms to 100 milligrams and beyond
- Weight of each capsule content is recorded, allowing traceability of samples that meet GMP requirements

## Capsules Can Be Filled with Drug Alone

- · Simplifies analytical development and stability requirements, reducing development time
- Reduces waste and eliminates the need for a powder blend
- System is able to fill capsules and a variety of small dose containers including: vials, tubes, blisters, and cassettes
- Precision closing of capsules

## **Optimization of the Filling Process**

- Compensates for variability in drug powder properties
- · Simplification of method development
- · Improved data transfer



# **Xcelodose® Capabilities**

#### Xcelodose® 600S Xcelodose® 120S

Throughput	up to 120 capsules per hour	up to 600 capsules per hour
Capsule Handling	manually loaded with dosing carousel customized to suit requirements	automatic with capsules being continuously fed through the system and filled
Dose Form	capsule, cartridge, cassette, blister, vial, tube, or other compact dose containers	capsule only sizes 00 - 4
Capsule Types	gelatin, hypromellose (HPMC), pullalun	gelatin, hypromellose (HPMC), pullalun
Footprint	dispensing system: 565mm x 385mm / control cabinet 600mm x 600mm	dispensing system: 670mm x 385mm / control cabinet 600mm x 600mm
Powder Feed	manual, facilitates bulk feed suitable for high dose weights	manual, automatic feed utilizing integral high throughput unit
Powder Type	powders, granules and beads	powders, granules and beads







