

Micro-Dosing and Powder-in-Capsule Formulations

>30 years' experience in advancing thousands of compounds to clinical studies



Micro-dosing is the process of dispensing a precise amount of drug substance into a capsule or bottle for use in early phase human studies. Lonza's Xcelodose® Precision Powder Micro-Dosing systems and market-leading experience in micro-dosing enable effective powder-in-capsule (PIC) evaluations and services for your preclinical studies. We can help you accelerate initial studies to determine if the drug substance should receive further investment, which is critical for cost-effective product development.

Extensive capability and capacity

Micro-dosing for PIC evaluations is a key component of our early stage product development offering aimed at optimized product design and speed to clinic. PIC programs are generally completed approximately 50% faster than traditional formulation development approaches — resulting in savings of up to six months to first-in-human studies. Our Xcelodose® equipment can accommodate a wide range of powders, including blends and highly potent compounds, in doses as low as 0.1 mg.

Our Center of Excellence for PIC studies in Tampa, Florida has integrated product development and manufacturing, and multiple Xcelodose® units to support both early design work and clinical manufacture of PIC.

Best practices

Our leadership in PIC development utilizing Xcelodose® technology includes more than 200 APIs with more than 600 batches processed. We've also developed a number of best practices, including:

- Expertise in API/capsule interaction considerations
- Expertise in sample preparation and capsule emptying techniques for optimized efficiency
- Evaluations of excipient/excipient blends on dispensing head operation
- Translation of API analytical methods to API-in-capsule methods
- Calibration system capability/protocols beyond Xcelodose® equipment standards.

	Tampa, Florida
Feasibility/GMP production	Xcelodose® 600/600S
High potency APIs	●
Product design and development	●
Solid dose CTM capabilities	●

Wide-ranging benefits with Xcelodose®

Lonza's Xcelodose® Precision Powder Micro-Dosing systems are the industry standard for enabling accurate and rapid PIC studies. They allow for precision weighing of drug substances into capsules from 0.1 mg to 100 mg per dose, depending on the physical characteristics of the drug substance and capsule size. Best-in-class filling accuracy (2% RSD) is achieved at typical speeds of 200–250 capsules per hour, dependent upon dose specifics. Xcelodose® units in product development and GMP production locations at Tampa are designed for capsule filling only.

Benefits for phase I-II studies include:

- Streamlined product development
 - Minimizes drug substance usage in formulation development
 - Eliminates excipient compatibility screening
 - Simplifies analytical and stability evaluations
- Increased efficiencies via programmable and precise dispensing of drug substance into capsules
- Provides supporting documentation, including weights for each capsule produced
- Cost control
 - Reduces waste
 - Minimizes analytical and formulation development costs
 - Allows for multiple strengths to be prepared for the clinic using the same process.

Lonza precision powder micro-dosing systems

Lonza Xcelodose® systems in the experimental area enable clients to use laboratory-grade material for dispensing head selection, filling-process evaluation and capsule compatibility, or to fill PIC for preclinical studies.

Xcelodose® 600/600S

Capsule sizes: Size 00 up to size 4

Filling range: 0.1 mg to 100 mg

Filling rate: 200–250 capsules/hour



Micro-dosing services are complemented by advanced technology selection methodologies for rapid formulation design, integrated micronization capability and phase-appropriate proprietary equipment. These capabilities, combined with our technology range and formulation expertise, allow Lonza to meet your target product profile and commercial objectives on a customized basis.

Learn more about how Lonza's micro-dosing and powder-in-capsule evaluations can help you enhance pre-clinical and clinical product development.

Contact us

Get in touch with the Small Molecules team to learn more. We work as one.



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