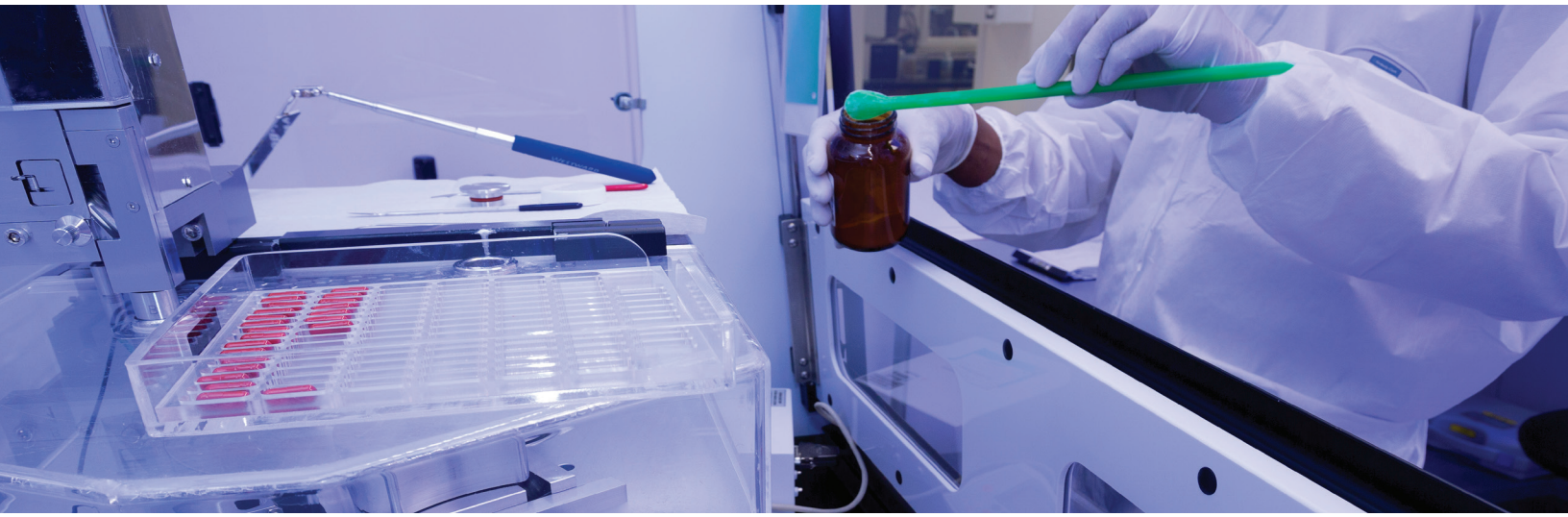
Micro-dosing and Powder-In-Capsule Evaluations

Capsugel® | Lonza Pharma & Biotech



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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. Capsugel's Xcelodose® Precision Powder Micro-Dosing systems and market-leading experience in micro-dosing enable premier 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 6 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 100 micrograms.

centers of excellence for PIC studies in Tampa, Florida and Ploermel, France have integrated product development and manufacturing, and multiple Xcelodose units to support both early design work and clinical manufacture of PIC.

	Tampa, FL	Ploermel, France
Feasibility	Xcelodose 120	Xcelodose 600
GMP Production	Xcelodose 600S	Xcelodose 600S
High Potency APIs	✓	✓
Product Design & Development	✓	✓
Solid Dose CTM Capabilities	✓	✓

Best Practices

Our leadership in PIC development utilizing Xcelodose technology includes more than 200 APIs with over 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

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Wide-Ranging Benefits with Xcelodose

Capsugel'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 200 mg per dose, depending on physical characteristics of the drug substance and capsule size. Best-in-class filling accuracy (2% RSD) is achieved at at typical speeds of 200-250 capsules per hour dependent upon dose specifics.[1] Xcelodose systems also accommodate the widest range of fill material as well as the widest array of receptacle types inclusive of capsules, vials and bottles. 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

Capsugel Precision Powder Micro-Dosing Systems

Capsugel 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. Separate units are utilized for cGMP production of clinical trial material utilizing two types of Xcelodose equipment.

Xcelodose® 120S

Capsule Sizes: Size 4 up to Size 00

Filling Range: 0.1mg (100mcg) up to 200mg[1]

Filling Rate: Typical 80-100 capsules/hour[1]

Xcelodose 600/600S

Capsule Sizes: Size 4 up to Size 00

Filling Range: 0.1mg (100mcg) up to 200mg[1]

Filling Rate: Typical 200-250 capsules/hour[1]

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 Capsugel to meet your target product profile and commercial objectives on a customized basis.

Learn more about how Capsugel's Micro-dosing and Powder-In-Capsule Evaluations can help you enhance pre-clinical and clinical product development.

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