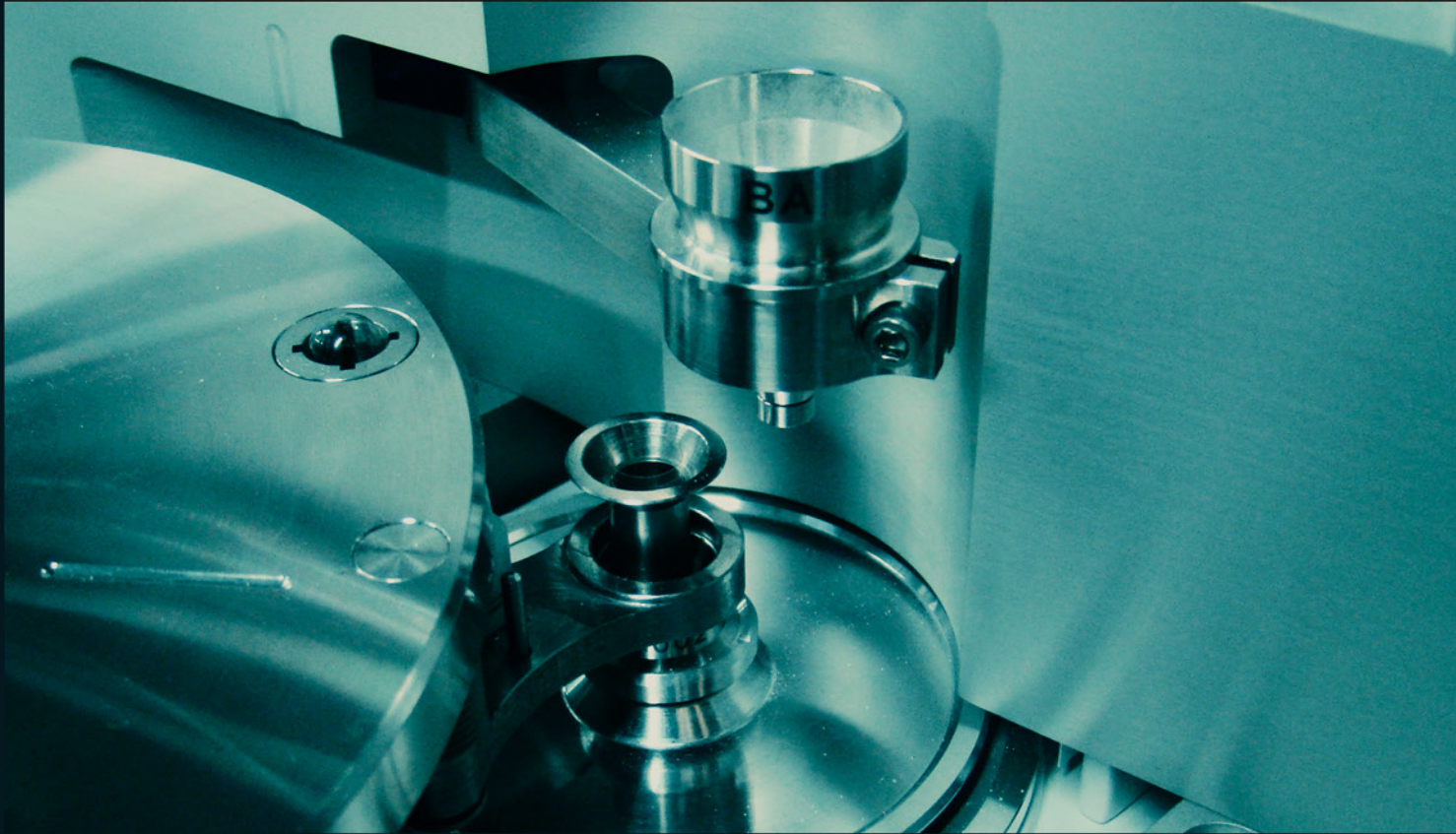


Lonza Engine™
Accelerate Innovation

Xcelodose® S

Powder Micro-dosing
System



Lonza

Even faster time to first-in-human studies

The innovative and automated way to precisely fill capsules without excipients or bulking agents

With the Xcelodose® system, creating manufacturing batches for clinical trials and small-scale production has never been easier or more precise.

That's because this unique technology allows companies to fill capsules with drug substances alone, thereby eliminating the need for excipient compatibility and preformulating activities. Not only can the Xcelodose® system precisely dispense amounts as low as 100 micrograms and up to 100 milligrams, but its sophisticated software also records the weight of the drug in every capsule.

Plus, it can accurately fill 600 capsules per hour for extended period of time.

By implementing the Xcelodose® system, pharmaceutical companies benefit from a shorter drug development process by reducing the need for costly and time-consuming stability

studies, not to mention the avoidance of labour costs and possible inaccuracies associated with hand filling.

This in turn reduces the time taken to reach the first-in-human clinical trial decision point, which allows an increase in throughput of candidate compounds for development.

- Allows filling of API direct into capsules, with no need for excipients, and can thereby save up to 6 months' development time by reducing the need for formulation development and stability testing
- Accurate drug records for the monitoring of batches and individual capsules - the weight of each capsule and event is recorded
- Particularly suitable for manufacture of Phase I clinical supplies
- Wide range of optional extras and accessories available

A full range of Xcelodose® accessories, parts and spares are available upon request.

Select the Xcelodose® system that meets your needs

Whether you require an automated or semi-automated version, Lonza has an Xcelodose® system to fit your needs. Both the Xcelodose® 120S and Xcelodose® 600S offer these robust features:

Highly consistent dose accuracy

- programmable and precise dispensing of dose weights from 100 micrograms to 100 milligrams
- weight of each capsule content is recorded, allowing traceability of samples that meets GMP requirements

Capsules can be filled with drug alone

- simplifies analytical and stability protocols, helping to reduce development time
- reduces waste and eliminates the need for a 'powder bed'
- ability to handle moisture-sensitive compounds, as filling can be performed at <5% RH
- Xcelodose® 120S system can fill capsules as well as a variety of small dose containers (vials, tubes, blisters, cassettes, etc.)
- more precise closing of capsules
- noise reduction
- power requirement reduced through removal of air compressor

Software automatically optimises the filling process

- designed for 21 CFR Part 11 compliance
- compensates for any variability in drug powder properties
- simple user interface with continuous data display and

- instructions to help set up conditions for new drug substances
- tighter user access security
- built-in UPS options
- user manual on-screen
- method development is simplified
- improved data transfer
- comes with flat-screen monitor and IP65 keyboard
- full audit trail traceability

Bench-top dispensing unit with separate control cabinet

- dispensing unit can be located up to 3 meters from the control cabinet via an umbilical cord
- can be used for formulation development, pre-clinical and clinical trial batch manufacturing within flowhoods, fume cupboards and other isolation or containment units
- quick-change parts can be used to switch between capsules sizes
- operates at either 110 or 240 volts

Additional options

- choice between 2g or 10g balance and easy swap
- taper head options
- full set of validation documents and GMP requirements available

Select the Micro-dosing system that meets your needs

| | XCELOLAB™ DISPENSER | XCELODOSE® 120 S SYSTEM | XCELODOSE® 600 S SYSTEM |
|----------------------------|--|---|---|
| Throughput | Single dispense | Up to 200 capsules per hour (dependent on operator input) | 600+ capsules per hour High throughput unit for long runs and greater fill weights |
| Capsule Handling | Manually loaded Automatically filled (semi-automatic indexing with carousel option) | Manually loaded with dosing carousel customised to suit requirements Semi-automatic indexing | Fully automatic capsules handling and filling |
| Dose Form | Blister, bottle, capsule, cartridge, cassette, tube, vial, bespoke on request | Blister, capsule, cartridge, cassette, tube, vial, bespoke on request | Capsule only - sizes 00 to 4 |
| Capsule Types | Gelatin, HPMC, pullulan | Gelatin, HPMC, pullulan | Gelatin, HPMC, pullulan |
| Footprint | Dispensing system: 575 x 430 mm control unit: n/a | Dispensing system: 565 x 385 mm control unit: 600 x 600 mm | Dispensing system: 670 x 385 mm control cabinet: 600 x 600 mm |
| Material Type | Powders, granules and beads | Powders, granules and beads | Powders, granules and beads |
| Material Properties | Cohesive, free-flowing, micronized, inhalation powder | Cohesive, free-flowing, micronized, inhalation powder | Cohesive, free-flowing, micronized, inhalation powder |

Technical Support and Service

Lonza's experienced service and support team will provide installation, validation packages and on-site training as requested. Also available are ongoing support and preventative maintenance agreements to keep your Lonza Engine™ equipment operating at optimal efficiency. For more information on services by our dedicated team of engineers and technicians, contact your Lonza sales representative or visit www.lonza.com.

Xcelodose® 120 S



Xcelodose® 600 S





Lonza

To order now or to obtain more information
about the equipment:
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Or contact your Lonza representative

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