

S[®] xcelodose

New Powder
Micro-dosing
System

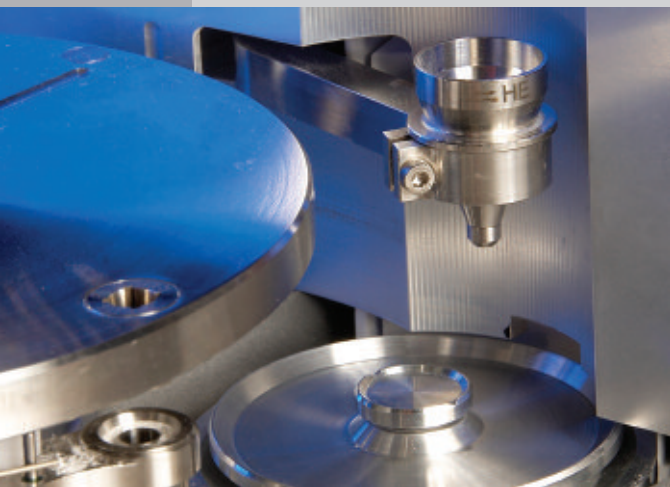
INTRODUCING THE NEW

Xcelodose[®] S



CAPSUGEL[®]
Quality
People and Products Working Together™

Even 'Faster Time to First in Man'



Xcelodose® S Benefits



- Even 'Faster Time to First in Man' with precision, speed and accuracy
- Fills with precision at speeds of over 600 capsules/hour at ~2% RSD – approximately 10x faster than filling by hand, and 50% greater throughput than the previous version of Xcelodose®
- Greater robustness over longer production runs
- Additional software functionality
- Integral High Throughput Unit available
- No internal pneumatics – machine is much quieter
- 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
- Doses as low as 100 micrograms for precise drug trials
- Capsule size change can be achieved in minutes – change parts sizes 00 to 4 available
- Can be tailored to fill any powder, including blends
- Particularly suitable for manufacture of Phase I clinical supplies
- Wide range of optional extras and accessories available

xcelodose® S

Even 'Faster Time to First in Man'

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 preformulation activities. Not only can the Xcelodose system precisely dispense amounts as low as 100 micrograms and up to 100 milligrams and beyond, 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 periods 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 man' clinical trial decision point, which allows an increase in throughput of candidate compounds for development.

Select the Xcelodose® System That Meets Your Needs

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

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 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 120 S 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 metres 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 capsule sizes
- operates at either 110 or 240 volts

Additional options

- choice between 2gm or 5gm balance and easy swap
- taper head options
- full set of validation documents and GMP requirements available
- Annual Maintenance Agreement available



	Xcelodose® 120 S	Xcelodose® 600 S
Throughput	up to 120 capsules per hour (dependent on operator)	600 capsules per hour (depending on level of precision required)
Capsule Handling	manually loaded with dosing carousel customised to suit requirements	automatic – capsules are continuously fed through the system and filled
Dose Form	capsule, cartridge, cassette, blister, vial, tube or other compact dose containers	capsule only – sizes 00 to 4
Capsule Types	gelatin, hypromellose (HPMC), pullulan	gelatin, hypromellose (HPMC), pullulan
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 utilising Integral High Throughput Unit
Powder Type	powders, granules and beads	powders, granules and beads

Health, Safety and Environment

The Xcelodose® S will operate in a normal laboratory environment or within a laminar flow or other suitable containment enclosure.

Cleaning Validation

The system is designed for easy clean down of surfaces in a GMP environment. Drug contact parts (all fabricated from 316 stainless steel) can be easily removed for cleaning and sterilisation if required. Other machine surfaces can be cleaned with a range of cleaning solutions.

Factory Support Team

Full factory support and after-sales service for the Xcelodose® S system is provided on a global basis by a dedicated team of engineers and technicians. For more information regarding factory support, visit www.innomech.co.uk/xcelodose.htm.



Capsugel offers a complete line of specialised products and services for the preparation of clinical trial materials, including the CFS 1200 capsule liquid filling and sealing machine. Visit our website at www.capsugel.com for more information.





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