



Summary of capabilities

Cincinnati, Ohio, US

Facility facts

Development workforce: ~150

Commercial workforce: ~650

Regulatory approval: US FDA, US DEA, ANVISA, MHRA, Japanese PMDA, Korean FDA, Taiwanese TFDA, Swedish MPA, Irish Medicines Board, German Inspectorate, Russian Inspectorate

Potency capability: CAT2, selected suites for CAT3 A/B

Controlled drug schedule registration: Manufacturer/analytical lab, CI-CV and List 1, Chemical export CII-CV, Distribution/import CIII-CV, and List 1 chemical

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Unique offering

Controlled and sustained-release solid oral dosage forms, osmotic release dosage forms (laser drilling), liquid-filled hard-shell capsules, controlled substance manufacturing, and abuse-deterrent forms.

Capabilities

- Liquid-filled hard-shell capsules with banding
- Dry granulation (roller compaction)
- Wet granulation
 - High-shear granulation (top driven and bottom driven)
 - Fluid bed granulation (top spray)
- Pelletization (extrusion and spheronization)
- Bottom spray precision coating (aqueous and non-aqueous)
- Hot melt extrusion (HME) — high-pressure TSE
- Single and double-sided rotary tablet compression (single and multi-layer)
- Tablet coating (aqueous and non-aqueous, functional and aesthetic coatings)
- Laser drilling
- Tablet printing (carrier bar and flatbed)
- Encapsulation (powder and beads [single and dual population])
- ASAP stability (Accelerated Stability Assessment Program)
- Compaction simulation and FT4 powder rheometer
- Non-GMP laboratory (manufacturing)
- Potent compound processing (Cat 3A)

Lifecycle by dosage form	Early development				Late development	Commercial supply		
	Formulation development	Analytical development	Phase I	Phase II	Phase III	Commercial scale-up	Tech transfer	Regulatory
Size/details								
Tablet/capsule	•	•	•	•	•	•	•	•
Liquid-filled hard-shell capsules	•	•	•	•	•	•	•	•
Powders/granules	•	•	•	•	•	•	•	•

Cincinnati key equipment list—development and commercial scale:

	Equipment (features/scale)	Capsules	Liquid-filled hard-shell capsules	Powders and granules	Tablets
Blending	V-Blenders (1-75 cu. ft.)	•		•	•
	Twin shell V-Blenders (2-16 qt, 15-2,100 L)	•		•	•
	In-bin blenders (4-60 cu. ft.)	•		•	•
Compounding	Tanks/kettles (10-1,000L)		•		
Granulation	High-shear granulators (1-1,200 L)	•		•	•
	Roller compactor — Gerteis (up to 400 kg/hr)	•		•	•
	Mills, screens (5-40 kg/hr)	•		•	•
	Chilsonators (5-100 kg/hr)	•		•	•
	Oscillator	•		•	•
Extrusion	Extruder and spheronizer (1-4 kg/hr)	•		•	•
	Hot melt high-pressure twin screw extruder (5-25 kg/hr)	•		•	•
Drying	Fluid bed dryers, top and bottom spray (2-1,300 L)	•		•	•
	Fluid air	•		•	•
	Tray ovens	•		•	•
Compression	Tablet presses, single and double-sided (585,000 tablets/hr)				•
	Bi-layer/tri-layer tablet presses (5,000-132,000 tablets/hr)				•
Coating	Tablet coaters (15"-30", 48", and 60" pans)				•
Laser	Tablet laser (150,000 tablets/hr)				•
Filling and banding	Liquid-filled hard-shell capsules filler and bander (500-80,000 capsules/hr)		•		
Encapsulation	Encapsulators with checkweigher, single or dual bead/powder (50,000-200,000 capsules/hr)	•			
	Manual encapsulator (2,000 capsules/hr)	•			
	Automatic loader encapsulator (3,000 capsules/hr)	•			
Visual inspection	Viswell (300,000 tablets/hr)				•
Packaging	Bottles	•	•		•
	Bulk	•	•	•	•
	Blistering	•	•		•
	Stick pack			•	

* For detailed equipment information, please contact your Thermo Fisher Scientific representative.

* Minimum and maximum batch sizes are not necessarily related to scale; batch size requirements are dependent on the project details.

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