ThermoFisher SCIENTIFIC

Summary of capabilities

Cork, Ireland

Facility facts:	
Regulatory approval:	FDA, HPRA
Potency capabillity:	Up to cat 3B
Contact info:	Currabinny Carrigaline, Co Cork, Ireland Tel: +353 21 437 8800

Unique offerings:

- Flexible small molecule API process development, scale-up and commercialization all within one integrated, FDA-inspected facility.
- Comprehensive capabilities to undertake a broad range of chemistries and supply API for all phases of development and commercialization.
- A center of excellence for the manufacture of highly potent APIs.
- Fully compliant with all applicable regulations and meets the most stringent production, quality, cGMP, safety, and environmental standards.

Specialized capabilities:

The site has extensive flexible and multipurpose facilities, including; Ability to support clinical and small volume commercial API supply (up to 2,500L), dedicated highly potent API up to Cat 3b projects, with reactors up to 16,000 L, on-site stability chambers and comprehensively equipped analytical development and QC laboratories. A center of excellence for sustainability, Cork has on-site waste treatment and a wind turbine.

Specialised capabilities include:

- Analytical method development and validation
- Process validation, optimization, and development
- Solid state assessment
- New process technology transfer and evaluation
- Manufacturing of API and registered intermediates under cGMP conditions from kilo scale to metric tones
- Range of milling options including air classifier, pin, and hammer mills
- Aqueous spray drying

Summary of capabilities

Item		Size/details	Development					Commercial supply		
			Process development	Analytical development	Preclinical/ phase I	Phase II	Phase III	Commercial scale-up	Technology transfer	Regulatory
Laboratories (12) and PAT equipment	PDS labs	785 m2, 36 fume hoods, 1 high containment hoods	•	•						
	Scale-up lab	6 fume hood	•							
	Potent compounds labs	167 m2, 11 fume hood		•						
	Analytical equipment	HPLC (UV, VWD, DAD, RI, MS), supercritical fluid chromatography (SFC), UPLC, LC-MS, NMR (400MHz), ion chromatography, FTIR (ATR, KBr, film), ICP, XRPD, malvern matersize 2000, sympatec, air jet sieve, ultrasonic sieve. UV spectometer, Karl Fisher (volumetric and potentiometric).	•	•	•	•	•	•	•	•
	P.D.S. equipment and lab PAT	HPLCs, GC, UPLC, Prep LC, Orbitrap LC MS, UPLC-MS, GC-MS, DSC, React IR, PAT in situ - pH; FTIR, Raman, Blaze: high resolution microscope quality images, advanced CLD (Chord Length disruption) and turbidity. Automated reactors, automated samplers. Multireactors; Mya reaction stations, parallel crystallization monitoring platform-HEL crystal SCAN & mettler toledo optimax/easmaxes. As well as a as very well-equiped development lab. 1L filter drier, pocket filters, Hydrogenation suite (glass and Hastelloy reactors).	•	•						
	Physical properties equipment	DSG, TGA, particle size, viscometers, SEM, DVS, miscroscopy instrumentation, bulk density, powder rheology, Gamlen powder compaction analyser, 2-D image analysis (Malvern Morphologi), XRD.	•	•						
	PAT plant equipment	Lasentec FBRM (crystallation monitoring only), UV and IR (reaction monitoring), mass Spec (drying endpoint), conductivity (separation).	•		•	•	•		•	

Summary of capabilities

Item			Size/details	Development					Commercial supply		
				Process development	Analytical development	Preclinical phase I	Phase II	Phase III	Commercial scale-up	Technology transfer	Regulatory
B1 commercial API production	Reactors	Glass-lined reactors	2,500L, 4,000L, 4,500L, 4,800L, 5,800L, 6,300L (-30 to 200°C)					•	•	•	•
		Hastelloy reactors	4,500L, 5,450L, 6,300L, 30 to 200°C					•	•	•	•
		Hydrogenation	2,200L (GLCS), 5,450L (Hastelloy), -30 to 200°C					•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging and discharging					•	•	•	•
		Filter dryers	(3m², 4m²) Hastelloy, (2m², 3m², 6m²) stainless steel					•	•	•	•
		Online milling/sieving	Hastelloy					•	•	•	•
B2 commercial API production	Reactors	Glass-lined reactors	4,500L, 6,300L, 8,000L, (-30 to 200°C)					•	•	•	•
		Hastelloy reactors	6,300L, -30 to 200°C					•	•	•	•
		Centrifuge	Stainless steel					•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging and discharging, FIBC discharging					•	•	•	•
		Filter dryers	(3m²) Hastelloy					•	•	•	•
		Online milling/sieving	Hastelloy					•	•	•	•
B3 clinical and commercial API production	Reactors	Glass-lined reactors	1,000L, 4,500L, 16,000L (-30 to 200°C)				•	•	•	•	•
		Hastelloy reactors	4,500L, 12,000L, -30 to 200°C				•	•	•	•	•
		Material charging	Big bag FIBC powder handling, powder transfer system				•	•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging and discharging				•	•	•	•	•
		Filter dryers	(0.8 m², 1.5 m², 6 m²,) Hastelloy				•	•	•	•	•
		Online milling/sieving	Hastelloy				•	•	•	•	•
		Particle size modification	Wet milling				•	•	•	•	•
B4 milling	Particle size modification	Air classifier mill	Hosokawa stainless steel					•	•	•	•
		Hammer mill	Fitz Mill stainless steel					•	•	•	•
		Cone mill	Kek stainless steel					•	•	•	•
		Aqueous spray dryer	PSD3 spray dryer					•	•	•	•
		Pin mill	Stainless steel			•	•	•	•	•	•
		Bead mills	Nylacast/netzsch stainless steel			•	•	•	•	•	•
		Online sieving	Stainless steel/Hastelloy			•	•	•	•	•	•

*Minimum and maximum batch sizes are not necessarily related to scale; batch size requirements are dependent on the project details
** Ready-to-use (RTU) contact parts for prefilled syringes and cartridges

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Item			Size/details	Development					Commercial supply		
				Process development	Analytical development	Preclinical phase1	Phase II	Phase III	Commercial scale-up	Technology transfer	Regulatory
B5 potent compound	Reactors	Glass-lined reactors	30L, 60L, (-30 to 200°C)			•	•	•	•	•	•
		Hastelloy reactors	50L, (-30 to 200°C)			•	•	•	•	•	•
		Hydrogenation	50L, (-30 to 200°C)			•	•	•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging and discharging			•	•	•	•	•	•
		Filter dryers	(0.035m^2) hastelloy			•	•	•	•	•	•
		GMP isolators	Hastelloy discharge gloveboxes			•	•	•	•	•	•
B6 commercial API production	Reactors	Glass-lined reactors	7,000L, 8,000L, (-30 to 200°C)					•	•	•	•
		Glass-lined headtanks	1,600L-6,000L					•	•	•	•
		Material charging	Powder transfer system, gloveboxes gharging					•	•	•	•
	Isolation drying	GMP isolators	Stainless steel gloveboxes charging					•	•	•	•
		Filter dryers	(3m^2) Hastelloy, (3m^2) stainless steel					•	•	•	•
		GMP isolators	Hastelloy discharge gloveboxes, FIBC discharging					•	•	•	•
B7 commercial API production	Reactors	Glass-lined reactors	4,000L (-30 to 200°C)				•	•	•	•	•
		Glass-lined headtanks	2,500L, -30 to 200°C				•	•	•	•	•
		Material charging	Stainless steel gloveboxes charging				•	•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging				•	•	•	•	•
		Filter dryers	(1.5 m^2) stainless steel				•	•	•	•	•
		Online milling/sieving	Stainless steel				•	•	•	•	•

For detailed capabilities and capacity information, please contact your Thermo Fisher Scientific representative.

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				Process development	Analytical development	Preclinical phase I	Phase II	Phase III	Commercial scale-up	Technology transfer	Regulatory
B8 potent compound and kilo scale	Reactors	Glass-lined reactors	100L, 160L, 250L & 400L (-30 to 200 °C)			•	•	•	•	•	•
		Hastelloy reactors	160L (-30 to 200 °C)			•	•	•	•	•	•
		Hydrogenation	160L (-30 to 200 °C)			•	•	•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging and discharging			•	•	•	•	•	•
		Filter dryers	(0.22m^2) Hastelloy (0.05m^2) Hastelloy			•	•	•	•	•	•
		GMP isolators	Hastelloy discharge gloveboxes			•	•	•	•	•	•
B9 flexible pilot plant	Reactors	Glass-lined reactors	630L, 900L, 1,600L, 2,500L (-30 to 200°C)			•	•	•	•	•	•
		Hastelloy reactors	900L, 2,500L, (-30 to 200°C)			•	•	•	•	•	•
		Hydrogenation	1,450L (-30 to 200°C)			•	•	•	•	•	•
	Isolation drying	GMP isolators	Hastelloy gloveboxes charging and discharging			•	•	•	•	•	•
		Filter dryers	(1.1 m^3) hastelloy, (0.7 m^3) hastelloy, (0.125 m^3) hastelloy			•	•	•	•	•	•
		GMP isolators	Hastelloy discharge gloveboxes			•	•	•	•	•	•

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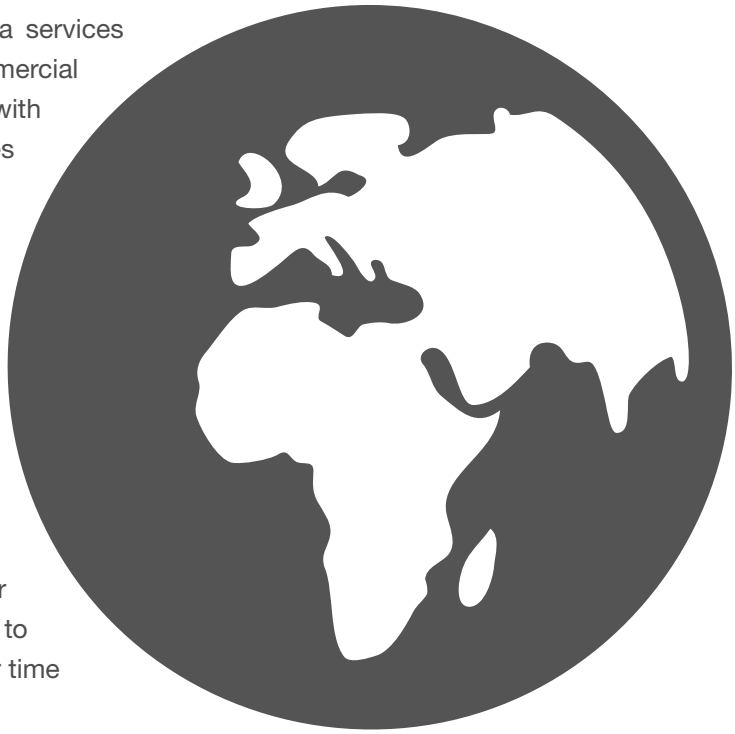

Discover the power of partnership and our global network.

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