



Cork, Ireland

Facility Facts:

Workforce:	~400
Regulatory Approval:	FDA, HPRA
Potency Capability:	Up to Cat 3B
Contact Info:	Currabinny Carrigaline, Co Cork Ireland Tel: +353 21 437 8800

Unique Offering:

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:

- New process technology transfer and evaluation
- Process optimization and development
- Solid state assessment
- Analytical method development and validation
- Process validation
- Pilot Plant (up to 2,500 L) to support clinical and small volume commercial API supply
- Manufacture API and registered intermediates under cGMP conditions from kilo scale to metric tonnes
- A range of flexible, multipurpose API production buildings with reactors up to 16,000 L
- Dedicated highly potent API facilities up to Cat 3b
- Range of milling capabilities including air classifier, pin and hammer mills
- Aqueous spray drying
- Comprehensively equipped analytical development and QC laboratories
- On-site stability chambers
- On-site waste treatment and wind turbine.

Item	Size/Details	Development					Commercial Supply		
		Process Development	Analytical Development	Pre-clinical/Phase I	Phase II	Phase III	Commercial Scale-Up	Technology Transfer	Regulatory
Laboratories (12) and PAT Equipment	Tech Dev Lab/ R&D Lab	785 m ² , 36 Fume Hoods, 1 High Containment Hoods	●	●					
	Scale-up Lab	46 m ² , 3 Fume Hoods	●						
	Potent Compounds Lab	167 m ² , 11 Fume Hoods		●					
	Analytical Equipment	HPLC (UV, VWD, DAD, RI, CAD, MS), UPLC, GC-MS, NMR (400 MHz), ion chromatography, FTIR (ATR, KBr, film, gas), ICP, DSC, TGA, microscopy, turbidity meter, refractive index, LOD, ROI, conductivity, titration (acid/base, chloride, KF), color analysis, particle size, GPC (RI, UV, light scattering). li-Process Control, Quality Control, Microbiology and Environmental testing. Method Development and Stability testing.		●	●	●	●	●	●
	Physical Properties Equipment	DSC, TGA, microscopy, turbidity meter, refractive index, conductivity, color analysis, particle size, GPC (RI, UV, light scattering).	●	●					
	PAT Plant Equipment	Lasentec FBRM (crystallisation), UV & IR (reaction monitoring), Mass Spec (drying endpoint), conductivity (separation).	●		●	●	●		●

Item			Size/Details	Development					Commercial Supply		
				Process Development	Analytical Development	Pre-clinical/Phase I	Phase II	Phase III	Commercial Scale-Up	Technology Transfer	Regulatory
B1 Commercial API Production	Reactors	Glass Lined Reactors	2500L, 4000L, 4500L, 4800L, 5800L, 6300L (-30 to 200 °C)					•	•	•	•
		Hastelloy Reactors	4500L, 5450L, 6300L, -30 to 200 °C					•	•	•	•
		Hydrogenation	2200L (SS), 5450L (Hastelloy), -30 to 200 °C					•	•	•	•
	Isolation Drying	GMP Isolators	Hastelloy Gloveboxes Charging & Discharging					•	•	•	•
		Filter Dryers	(3 m ² , 4 m ²) Hastelloy, (2 m ² , 3 m ² , 6 m ²) SS					•	•	•	•
	OnLine Milling/Sieving	Hastelloy					•	•	•	•	
B2 Commercial API Production	Reactors	Glass Lined Reactors	4500L, 6300L, 8000L (-30 to 200 °C)					•	•	•	•
		Hastelloy Reactors	6300L, -30 to 200 °C					•	•	•	•
		Centrifuge	Stainless Steel					•	•	•	•
	Isolation Drying	GMP Isolators	Hastelloy Gloveboxes Charging & Discharging					•	•	•	•
		Filter Dryers	(3 m ²) Hastelloy					•	•	•	•
	OnLine Milling/Sieving	Hastelloy					•	•	•	•	
B3 Commercial API Production	Reactors	Glass Lined Reactors	1000L, 4500L, 16000L (-30 to 200 °C)				•	•	•	•	
		Hastelloy Reactors	4500L, 12000L -30 to 200 °C				•	•	•	•	
		Material Charging	Big Bag FIBC Powder Handling				•	•	•	•	
	Isolation Drying	GMP Isolators	Hastelloy Gloveboxes Charging & Discharging					•	•	•	•
		Filter Dryers	(0.8 m ² , 1.5 m ² , 6 m ²) Hastelloy					•	•	•	•
	OnLine Milling/Sieving	Hastelloy				•	•	•	•		
B4 Milling	Reactors	Air Classifier Mill	Hosokawa Stainless Steel					•	•	•	•
		Hammer Mill	Fitz Mill Stainless Steel					•	•	•	•
		Cone Mill	KEK Stainless Steel					•	•	•	•
		Aqueous Spray Dryer	PSD3 Spraydryer					•	•	•	•
	Isolation Drying	Pin Mill	Stainless Steel			•	•	•	•	•	•
Bead Mills		Nylacast / Netzsch Stainless Steel			•	•	•	•	•	•	
	OnLine Sieving	Stainless Steel/Hastelloy			•	•	•	•	•	•	
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 & Discharging			•	•	•	•	•	•
		Filter Dryers	(0.035 m ²) Hastelloy			•	•	•	•	•	•
	GMP Isolators	Hastelloy Discharge Glovebox			•	•	•	•	•	•	
B6 Commercial API Production	Reactors	Glass Lined Reactors	8000L (-30 to 200 °C)					•	•	•	•
		Glass Lined Reactors	7000L (-30 to 200 °C)					•	•	•	•
		Material Charging	Powder Transfer System Gloveboxes Charging					•	•	•	•
	Isolation Drying	GMP Isolators	Stainless Steel Gloveboxes Charging					•	•	•	•
		Filter Dryers	(3m ²) Hastelloy					•	•	•	•
	GMP Isolators	Hastelloy Discharge Glovebox					•	•	•	•	
B7 Commercial API Production	Reactors	Glass Lined Reactors	4000L (-30 to 200 °C)				•	•	•	•	•
		Glass Lined Heaktanks	2500L (-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					•	•	•	•	
B8 Potent Compound & 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 & Discharging			•	•	•	•	•	•
		Filter Dryers	(0.22 m ²) Hastelloy, (0.05 m ²) Hastelloy			•	•	•	•	•	•
	GMP Isolators	Hastelloy Discharge Glovebox			•	•	•	•	•	•	
B9 Flexible Pilot Plant	Reactors	Glass Lined Reactors	630L, 900L, 1600L, 2500L (-30 to 200 °C)			•	•	•	•	•	•
		Hastelloy Reactors	900L, 2500L, (-30 to 200 °C)			•	•	•	•	•	•
		Hydrogenation	1450L (-30 to 200 °C)			•	•	•	•	•	•
	Isolation Drying	GMP Isolators	Hastelloy Gloveboxes Charging & Discharging			•	•	•	•	•	•
		Filter Dryers	(1.1 m ²) Hastelloy, (0.75 m ²) Hastelloy, (0.125 m ²) Hastelloy			•	•	•	•	•	•
	GMP Isolators	Hastelloy Discharge Glovebox			•	•	•	•	•	•	