

Milton Park, Oxford, UK

Facility Facts:

Regulatory Approval:	MHRA
Potency Capability:	Cat 3a No cytotoxics, no hormones, no steroid and no β -lactam antibiotics
Controlled Drug Schedule Registrations:	None
Contact Info:	151 Milton Park, Milton, Abingdon, OX14 4SD UK Tel: + 44-1235-433010 Fax: + 44-1235-834261

Unique Offerings:

Fast, flexible early phase development. Pediatric formulation development. Early Development facility with strong links to both larger scale development and clinical services sites for clinical packaging, labelling, distribution and QP release services.

Specialized Capabilities:

Solubility enhancement

- non-GMP Spray Drying
- Lipids

Oral Solid Dose formulation development

- Tablets
- Capsules
- Analytical method development and validation

Quick to Clinic™

- Phase appropriate formulation
- Clinical batch manufacture
- Focus on Speed
- Clinical packaging, labelling
- QP Release Services

Clinical batch manufacture and scale up

- Tablets
- Capsules
- Pelletization
- Oral liquids
- Roller compaction
- Xcelodose
- Sachet filling
- Disposable technologies

Lifecycle by Dosage Form:

Dosage Forms	Early Development				Late Dev	Commercial Supply		
	Formulation Development	Analytical Development	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer	Regulatory
Conventional Solid Dose	Immediate Release Tablets	•	•	•	•			
	Powder Filled Capsules	•	•	•	•			
	Powders / Granules / Coated Beads	•	•	•	•			
Specialized Solid Dose	Controlled Release Tablets	•	•	•	•			
	Microtablets	•	•	•	•			
	Liquid Filled Capsules	•	•	•	•			
	Coated Tablets	•	•	•	•			
	Tablets / Beads in Capsules	•	•	•	•			
Quick to Clinic™	Blend in Capsule	•	•	•	•			
	API in Capsule	•	•	•	•			
	Blend in Bottle	•	•	•	•			
	API in Bottle	•	•	•	•			

Milton Park Key Equipment List – Solid Dose:

Equipment (Features / Scale)		Immediate Release Tablets	Powder Filled Capsules	Powders / Granules / Coated Beads	Controlled Release Tablets	Microtablets	Liquid Filled Capsules	Coated Tablets	Tablets / Beads in Capsules
Solubility Enhancement	Buchi B290 spray dryer with inert loop – up to 200g/lot	•	•						
Granulation and drying	Hobart mixer – up to 5kg	•	•	•	•	•		•	•
	Diosna P1–6 + Diosna Minilab – up to 7.5kg	•	•	•	•	•		•	•
	Vector roller compactor – up to 200g/hour	•	•	•	•	•		•	•
	Caleva Extruder (20 & 35)			•					•
	Cavela Spheronizer Multibowl & 380			•					•
	Glatt TMG granulator with bowl sizes from 0.5 L to 8 L. Batch size, up to 10 kg (based on sublots)	•	•	•	•	•			•
Midi-Glatt fluid bed dryer capable of processing up to 1.5 kg of material – Batch size, up to 10 kg (based on sublots)	•	•	•	•	•			•	•
Milling and blending	Pharmatech AB400 – up to 20kg	•	•	•	•	•		•	•
	Turbula mixers / Drum Blenders – up to 10kg	•	•	•	•	•		•	•
	Comil (U5 & 197) – up to 50kg	•	•	•	•	•		•	•
Encapsulation – Size 00 to Size 4	Torpac encapsulation system – up to 50,000 / batch						•		•
	Mettler Quantos system – from 5mg fill weight, up to 2,000 / batch		•						
	Xcelodose –1mg to 100mg fill weight, up to 8,000 / batch		•						
	Perry Accofil dosing system – from 20mg dose, up to 10,000 / batch		•						•
	Schaefer Liquid Filled Hard Capsule filler / bander – up to 5000 / batch						•		
	Profil overencapsulator – manual filling, up to 10,000 / batch		•						•
MG2 FlexaLAB- up to 20kg, 3000 capsules/hr		•						•	
Tableting	Riva Piccola – up to 20kg	•			•	•		•	•
Coating	Vector LCDS – up to 6.5kg				•			•	
Packaging	KControls 4400TX Sachet / Bottle filler, 50mg – 80g fill – up to 1000/hr			•					
	Senator Sachet Sealer			•					
	SEPHA EZ-Blister packer – Coldform (Alu-Alu, Dessiflex) and Thermoform (PVC, PVdC, ACLAR)	•	•		•	•	•	•	•

* 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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