Summary of capabilities

Swindon, UK

Facility facts:

Workforce: ~600

Regulatory approval: MHRA, US FDA, ANVISA

Potency capability: Up to Cat 3b

Controlled drug Schedule 3 & 4 plus Precursor

schedule registrations: Category 1 substances

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Unique offering:

The Swindon facility specializes in integrated sterile liquid and lyophilized product development and commercial manufacturing, including high potency products and LVP.

Specialized capabilities:

- Sterile lyophilized products
- Commercial fill finish lines
- · Primary and secondary packaging vials
- Development and commercial supply of novel dosage forms
- Facility design and build for unique manufacturing processes
- LNP capabilities
- mRNA process development experience
- Process development
- Engineering/process expertise
- Extensive complex technology transfer experience
- · Qualified person expertise

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
Liquid vial					•	•	•	•
Lyophilized vial					•	•	•	•

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



Swindon key equipment list:

Equipment (features/scale)*		Tablets &mini tablets	High potency
	Mixing tanks – Stainless steel	•	•
Blending	Disposable flexible containers – fully disposable compounding and receiving vessels	•	•
Washing	Vial washer	•	•
Depyrogenation	Depyrogenation	•	•
Component sterilisation and drying	Autoclave	•	•
Filling and stoppering	Vial fillers (Bausch + Strobel & Optima)	•	•
	ATEC stopper processing	•	•
Lyophilization	Lyophilizer (2 x 15m2, 1 x 30m2, optima lyophilises	•	•
Capping	Vial Capper / crimper (C-RABS, isolator)	•	•
Inspection and packaging	Auto visual Inspection (AVI)	•	•
	External vial washer (IMA Hydra 300) Semiautomatic AVI	•	•
	Labeler	•	•
	Cartoner	•	•
	Manual inspection	•	•

^{*} 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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