

A summary of the Aptuit pilot plant capabilities



Site	Clinical			Commercial
	Phase I	Phase II	Phase III	
UK	✓	✓	✓	✓
Italy	✓	✓		
Batch sizes	1 - 2 kg	3 - 50 kg (maximum batch 120 kg)		up to 120 kg in 200-1600L vessels
Scale	20L glass vessels	20-1600L glass, glass lined steel, hstelloy		100-1600L
Equipment	Pressure hydrogenation to 40 Bar (Ver - 20L) Cryogenic to -80°C (Italy - 20L) PAT tools: Lazentech Raman	Cryogenic to -80°C (Oxford - 400L only) Hydrgenation (UK - up to 1600L and 7barG) Enclosed Hastelloy Filter Dryers High potent handling to 0.5ug/m3 at up to 1600L scale (UK)		
Containment	OEB 4	OEB 4 for 20-1600L		OEB 4 to 1600L

Site	Development	Small scale-up	Development for fixed vessel	CPP study	Validation	Commercial process
UK	✓	✓	✓	✓	✓	✓
Italy	✓	✓	✓	✓		
	UK and Italy Route scouting Route selection	20 and 100L	UK and Italy - fit for purpose. Move quickly to 20-100L to produce tox batches	At UK and Italy	At UK Validation at 100-1600L scale	At UK Up to 1600L scale
	Solid sate activities Salt screens Polymorph studies Control of Particle size by crystallisation			DOE studies Automated reaction station		
Tech transfer supported by Process Chemistry team (24/7 support)						

