



The Gainesville facility was built in 1981 by Elan Corporation to be its first manufacturing facility in the US. Elan managed and launched modified-release solid oral dosage products from Gainesville until the merger of Elan Drug Technologies with Alkermes in 2011. The facility remained under Alkermes leadership until 2015 when Recro Pharma purchased the GMP facility and rights to the legacy Elan products. In addition to the continued manufacturing of these commercial pharmaceutical products, the Recro Gainesville site operates as a CDMO, performing contract development and manufacturing for pharmaceutical and biopharma companies. The core expertise of the site remains in the area of modified release solid oral dosage form development and manufacturing, custom release profile development, DEA controlled substance registration, and strong regulatory support, which includes FDA interactions on behalf of sponsor companies.

FACILITY FACTS:

Development/Commercial Workforce: 196

Regulatory Approval: US FDA, US DEA, Foreign Health

Ministries Inspections:

Danish Inspectorate, ANVISA (Brazil),

Turkish MOH

POTENCY CAPABILITY: CAT2, CAT3A

CONTROLLED DRUG

SCHEDULE REGISTRATIONS:

DEA Licenses:

- **Importer:** Schedule II
- **Analytical Lab:** Schedule I, II, IIN, III and IV
- **Manufacturer:** Schedule II, IIN and III
- **Exporter:** Schedule II and IIN

SPECIALIZED OFFERINGS:

Controlled and sustained release solid oral dosage forms, multi-particulate controlled release, controlled substances manufacturing and regulatory support/submission (IND, NDA, DMF, eCTD, FDA meeting support).

SPECIALIZED CAPABILITIES:

Tablet development:

- Single and bi-layer tablets
- Controlled and immediate release
- Direct compression
- Fluid-bed granulation
- Rotor granulation
- Tablet coating (solvent capable)

Multi-particulate capsule development:

Wurster processing (solvent capable)

- Drug layering
- Polymer coating

Rotor processing (solvent capable)

- Granulation
- Direct pelletization
- Powder layering
- Polymer coating

Encapsulation

- Two-piece hard gelatin capsules
- Up to 4 individual bead fills in the same capsule

Contact Info:

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LIFE CYCLE BY DOSAGE FORM								
Size / Details	Early Development			Late Dev			Commercial Supply	
	Formulation Development	Analytical Development	Phase I	Phase II	Phase III	Commercial Scale-up	Tech Transfer	Regulatory
Tablets	•	•	•	•	•	•	•	•
Capsules	•	•	•	•	•	•	•	•

ANALYTICAL EQUIPMENT	
Chromatography	HPLC – Waters Alliance Systems with dual-wavelength UV, and PDA detectors
	UPLC – Waters Acquity Systems with QDa, dual-wavelength UV, and PDA detectors
	GC – Agilent 6890 with FID and TCD
Spectroscopy	FTIR – Spectrum One ES FT-IR spectrometer
	UV/Vis – HP/Agilent spectrophotometers
	Raman – TruScan RM handheld Raman spectrometer
Lab Automation	SOTAX TPW 3 – Automated sample preparation system for assay, related substances, blend and content uniformity analysis
Dissolution	Dissolution baths – Hanson with auto-samplers
	Agilent automated UV/Vis analysis
	Waters 2695D – Combination HPLC/dissolution auto-sampler
	Distek automated fiber optic analysis
	SOTAX AT MD – Automated dissolution system with online UV
Other	Particle size analysis – Horiba LA950A2 laser light scattering Horiba Camsizer
	Moisture analysis – Karl Fischer, Halogen moisture analyzer
	Air sampling – Microbial and total particulates
	Total Organic Carbon (TOC)
	Polarimetry, melting point, densitometer, refractive index

KEY EQUIPMENT LIST – DEVELOPMENT SCALE		
	Equipment	Scale
Blending	PK Blend Master (V-Blender)	4 – 16 qt
	PK Blend Master (bin blender with intensification)	4 – 16 qt
	Ima Maxi-Tumbler	30 – 700 L
Fluid Bed Processing	Glatt GPCG-3	7” Wurster, 10 L granulation
	Glatt GPCG-30	18” Wurster, 100 L granulation
Rotor Processing	Vector Granurex GX-40	40 cm rotor, 1 - 7 kg
Milling	Quadro Comil 197AS	
	Fitzpatrick hammer mills L1A and M5A	
Compression	Korsch XL100 Pro	8-station D tooling 20 K per hour
Tablet Coating	L.B. Bohle BTC 100 (solvent capable)	25 - 130 L
Oven Drying	Casburt and Gruenberg tray ovens (temperature and humidity control)	80 trays
Encapsulation	Bosch GKF 400 (2 independent bead fills)	19 K capsules per hour
Packaging	Bottles (square, 40 cc – 500 cc and up to 500 units/bottle)	1,600 bottles per hour
	Bottles (round, 40 cc – 500 cc and up to 500 units/bottle)	1,600 bottles per hour

KEY EQUIPMENT LIST – COMMERCIAL SCALE		
	Equipment	Scale
Blending	Ima Maxi-Tumbler	30 – 700 L
Fluid Bed Processing	Glatt GPCG-120 fluid bed coater	32” Wurster
	Glatt GPCG-30 fluid bed coater	18” Wurster, 100 L granulation
Rotor Processing	Vector Granurex GX-125	125 cm rotor, 30 - 200 kg
Dry Granulation	Alexanderwerk WP-200	10 - 250 kg per hour
Milling	Quadro Comil 197AS	
	Fitzpatrick hammer mill D6A	
Compression	Fette FE55 (bi-layer capable)	60 station – 400 K per hour
Tablet Coating	L.B. Bohle BTC 100 (solvent capable)	25 - 130 L
Oven Drying	Casburt and Gruenberg tray ovens (temperature and humidity control)	80 trays
Encapsulation	MG2 encapsulators (4 independent bead fills)	96 K capsules per hour
Packaging	Bottles (square, 40 cc – 500 cc and up to 500 units/bottle)	1,600 bottles per hour
	Bottles (round, 40 cc – 500 cc and up to 500 units/bottle)	1,600 bottles per hour

* Minimum and maximum batch sizes are not necessarily related to scale; batch size requirements are dependent on the project details.

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