



Greenville, NC USA

Oral Solid Dose Drug Product Facility Facts:

Workforce: ~1,500 (OSD & Sterile)

Regulatory Approval (key): FDA, Mexican MoH, KFDA, EMA, PMDA, Turkish MoH, TGA – Australia, NC Dept of Agriculture, ANVISA, SFDA

Potency Capability: Up to Cat 3a

Controlled Drug Schedule Registrations: Manufacturer / Analytical Lab Schedules 1, 2, 2N, 3, 3N, 4, 5, L1 Import Schedules 3N, 4 Export Schedules 2, 2N, 3N, 4

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Specialized Capabilities:

Continuous Manufacturing for OSD

- Clinical and Commercial scale
- Process development and validation
- Tablets and capsules
- Direct blending
- Dry / Wet granulation*

Conventional OSD – Commercial Manufacturing

- Tablets, Capsules, Beads
- Spray Granulation
- Multi-pellet / Dose Capsule Filling
- API – Polymer Bead Layering
- Table-in-Tablet
- Extrusion – Spheronization

* Process development from Phase I to commercial

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
Continuous Manufacturing – Tablets / Capsules	•		•	•	•	•	•	•
Conventional Oral Solid Dose – Tablets / Capsules	•				•	•	•	•
Conventional Oral Solid Dose – Powders / Granules	•				•	•	•	•

Greenville NC Key Equipment List – Conventional Solid Dose Commercial Scale

Equipment (Features / Scale)		Capsules	Powders, Granules & Beads	Tablets
Blending	Slant Cone (85L) — Intensifier bar	•	•	•
	V Blender (142L) — Intensifier bar	•	•	•
	Bin Blender (212L, 425L, 595L, 850L, 1189L and 1585L)	•	•	•
Compounding	Compounding Tanks (Varying sizes) — pneumatic agitators	•	•	•
	Jacketed Premix Tanks (Product specific) — pneumatic agitators	•	•	•
Granulation	Roller Compactor (Fitzpatrick IR 520)	•	•	•
	High Shear Granulator: Vertical (PMA 150, PMA 300 PMA 1200, Spectrum 1200)			
	Horizontal (Lodige 368L and 1218L)	•	•	•
	Low Shear Granulator: Hobart (140 qt) and Baker Perkins (378L)	•	•	•
Milling and Sifting	Milling: Quadro Comil (194, 196, and 197), Fitzmill (U and D), Frewitt Mill	•	•	•
	Vibratory sifting: Russel Finex (22 inch single screen and 36 inch double screen)			
	Sweco (48 in double screen with vibrasonic)	•	•	•
	Bead Manufacturing Glatt GPCG-200 (Wurster) (985L) X 2			
Extrusion and Spheronization	LCI Twin Dome Extruder (TDG-100)	•	•	•
	LCI Marumeizer Spheronizer	•	•	•
	Nica S 700 Spheronizer	•	•	•
Drying	Glatt WSG 120 (420 lit) — Top spray (Solvent capable)	•	•	•
	Glatt WSG 500 (1595 lit) — Top spray (Solvent capable)	•	•	•
	Glatt WST 500 (1595 lit) — Top spray	•	•	•
	Forced air Tray dryers — (3) Units (44 trays per dryer)	•	•	•
Compression	Tablet Presses (Fette) — 2090 (B Tool 36 station) X3, 3200 (B Tool 75 station segmented)			•
	Tablet in Tablet (Kikusui) — Aquarius (B Tool 61 station)			•
	Bi-Layer Tablet Press (Fette) — 3090 (B Tool 61 station)			•
Coating	Thomas Accela-Cota: 48 inch pan X 8, 60 inch pan X 1			•
Encapsulation	Bead Fill: MG2 Futura x 5	•		
	Powder Fill: H&K 1500 x 3	•		
	Bead and Powder Fill: IMA Matic 90 X 3	•		
Weight Checker	Bosch KKE (2000 and 2500)	•		
	IMA Precisia (120)	•		
Printing	Ackley			•
Packaging	Blistering	•		•
	Bottles	•		•
	Bulk	•	•	•
	Optel equipment for packaging serialization	•	•	•

* 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.