

Manatí, Puerto Rico

Facility Facts:

Commercial Workforce: ~519

Regulatory Approval: US FDA, US DEA, ANVISA, EMA, MoH (Turkey), MPA Sweden, KFDA, Kenya, Uganda, Belarus, Russia, NAFDAC

Potency Capability: Cat 2, Cat 3a and 3b (one with dry blend & compression equipment, and the other with FBD granulation/ high shear mixing, bin blending, encapsulation & capsule banding) equipment.

Controlled Drug Schedule Registrations: Manufacturer Registration Schedule II, III, III-N, IV, V, Listed C. Analytical Registration Schedule II, II-N, III, III-N, IV, V, Listed C

Contact Info: State Road 670 Km. 2.7 Manatí, PR 00674
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Unique Offering:

Oral powders and medium to high volume products

Specialized Capabilities:

- Solvent Granulation
- Powder in a Bottle
- Delayed / Extended / Controlled Release
- Aqueous and Solvent Coating
- Pellets encapsulation
- Micro tablets encapsulation
- Powder encapsulation
- Multi-API Granulations
- Hygroscopic Products — with low humidity environment capability
- Thermoformer clam shell equipment for secondary packaging
- Aqueous and Solvent (High Shear) Granulation
- Tablets encapsulation
- Tablet within tablet
- Active Coating
- High Potent Compounds

Lifecycle 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
Tablet					•	•	•	•
Fast Dispersible Tablet					•	•	•	•
Powders/Granules					•	•	•	•
Powder filled capsules					•	•	•	•

Manatí Key Equipment List:

Equipment (Features / Scale)		Capsules	Powders & Granules	Tablets
Blending	V-Blender (56 – 4,257 L)	•	•	•
	Bin Blender (125 – 3000 L)	•	•	•
Granulation and Drying (Solvent & Aqueous)	High Shear Granulator (Diosna P-800 / PMA / Zanchetta Rotto F-900, Up to 1200 L)	•	•	•
	Mill	•	•	•
	Fluid Bed Dryer/Granulator (Aeromatic, Niro, Vector / 1100 to 1200L)	•	•	•
Compression	Fette 3090 / 3200 – 49 stations 2 sided D size			•
	Fette FE-75 – 75 stations 2 sided			•
	Kikusui – 42 station single side			•
Coating	Accela (48" aqueous, 48" solvent)			•
	Accela 60" DLZ aqueous			•
Printing	Ackley Printer – (High speed / vision system)			•
Encapsulation	IMA Matic 90 – 1500 cpm	•		
	Adapta 100 – (1666 cpm)	•		
	Capsule Banding – (1533 cpm)	•		
Packaging	Bottles (plastic & glass, square & round)	•	•	•
	Bulk	•	•	•
	Neck banding	•		•
	Clam Shell	•		•
	Serialization and aggregation	•	•	•

* 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.