

Greenville, NC USA

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
Contact info:	5900 Martin Luther King Jr. Hwy Greenville, NC 27834-8628 USA Tel: +1 252 707 4376

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	Gemco Slant Cone (85L) — Intensifier bar capability	•	•	•
	Patterson Kelley V blender (142L) — Intensifier bar capability	•	•	•
	Tote Systems Bin Blender (212L, 425L, 595L, 850L, 1189L, and 1585L)	•	•	•
	Matcon Bin Blender (595L and 1500L)	•	•	•
Compounding	Compounding Tanks (varying sizes) — pneumatic agitators	•	•	•
	Jacketed Premix Tanks (varying sizes) — pneumatic agitators	•	•	•
Granulation	Fitzpatrick IR 520 Roller Compactor — Integrated D6A Fitzmill	•	•	•
	High Shear Vertical Granulator (PMA 300L and PMA 1200L) — PMA300 solvent capability	•	•	•
	High Shear Vertical Granulator —vacuum drying capability (Spectrum 1200L) — solvent capability	•	•	•
	High Shear Horizontal Granulator (Lodige 368L and Lodige 1220L) — solvent capability	•	•	•
	Top Spray Fluid Bed Dryer (Glatt WSG 120 (433L), Glatt WSG 500 (1597L)) — solvent capability	•	•	•
	Top Spray Fluid Bed Dryer (Glatt WST 500 (1597L))	•	•	•
	Low Shear Vertical Granulator — Hobart Mixer (132L)	•	•	•
	Low Shear Horizontal Granulator — Baker Perkins Mixer (378L)	•	•	•
Bead manufacturing	Wurster coating — Glatt GPCG-200 (985L) — solvent capability	•	•	
	Wurster coating — Glatt GPCG-200 (985L)	•	•	
Milling and sifting	Milling: Quadro Comil (194, 196, 197, and U20)	•	•	•
	Milling: Fitzpatrick Fitzmill (U and D6A)	•	•	•
	Milling: Frewitt Oscillating Mill (MF6)	•	•	•
	Vibratory Sifting: Sweco 48 inch (single or double screen with Vibrasonic)	•	•	•
	Vibratory Sifting: Russel Finex 36 inch (single or double screen)	•	•	•
	Vibratory Sifting: Russel Finex 22 inch (single screen)	•	•	•
Extrusion and spheronization	Extruder: LCI Twin Dome Extruder TDG-100	•	•	•
	Spheronizer: LCI Marumerizer Spheronizer	•	•	•
	Spheronizer: Nica S 700	•	•	•
Drying	Fluid Bed Dryer: Glatt WSG 120 (433L), Glatt WSG 500(1597L) — solvent capability	•	•	•
	Fluid Bed Dryer: Glatt WST 500 (1597L)	•	•	•
	Forced Air Tray Ovens: Despatch - 3 dryers with 44 trays per dryer	•	•	•
Compression	Fette 2090 — Single sided, B Tool (36 Station) / D Tool (29 Station) / BB Tool (43 station)			•
	Fette 3090 — double sided or bilayer, B Tool (61 station) / D Tool (49 station)			•
	Fette 3200 — Double sided, B Tool (75 station) / D Tool (49 station)			•
	Kikusui Aquarius — Tablet in Tablet, B Tool (45 Station)			•
Coating	Thomas Accela-Cota: 48 inch pan—solvent capability			•
	Thomas Accela-Cota DXL: 60 inch pan — solvent capability			•
Encapsulation	MG2 Futura — multi bead fill and powder encapsulation	•		
	IMA Matic 90 — single bead or powder encapsulation	•		
	IMA Practica — single bead or powder encapsulation	•		
	H&K1500 —powder encapsulation	•		
Capsule weight checker	Bosch KKE (2500)	•		
	IMA Precisia (120)	•		
Printing	Ackley Tablet Printer			•
Packaging	Bottle packaging: bundle — optel equipment for packaging serialization	•		•
	Bottle packaging: carton	•		•
	Blister packaging: carton	•		•
	Bulk packaging	•		•

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

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Potency capability:	Sterile dose up to Cat 3b
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Capabilities:

Sterile dosage forms

- Sterile liquid vials
- Sterile lyophilized vials
- Prefilled syringes and cartridges
- Disposable and dedicated product contact pathway
- Biopharmaceuticals
- Terminal Sterilization
- Peristaltic Filling System
- Small molecules
- Scale up
- Technology Transfer

Unique offering—sterile injectables drug product:

- Integrated sterile liquid and lyophilized product development for biologics, highly-potent compounds, and small molecules

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 vials	•	•	•	•	•	•	•	•
Lyophilized vials	•	•	•	•	•	•	•	•
Prefilled syringes					•	•	•	•
Prefilled cartridges					•	•	•	•

Greenville NC key equipment list—sterile dose commercial scale:

Equipment (Features / Scale)		Liquid vials	Lyophilized vials	Prefilled syringes	Cartridges
Compounding	Stationary jacketed tanks up to 2000 L (L1)	•			
	Portable jacketed tanks up to 1000 L (L2, 3) and disposable bag technology	•	•		
Washing	Automated vial washers on each line with speeds up to 400 vpm	•	•		
	Bosch on commercial lines	•	•		
Depyrogenation	In line dry heat depyrogenation tunnels (L1, 2, 3; all Bosch)	•	•		
Component sterilization and drying	North Stoppers — Smeja Automated Processors, 120 L and 280 L capacity (L1, 2, and 3) Line 2, 3 — RTS stoppers in addition to Smeja process	•	•		
	Overseals — steam autoclave for all lines	•	•		
Filling and stoppering	L1 — 12 Head Bosch Rotary Filler, positive displacement ceramic pumps, 5 mL – 50 mL vials	•	•		
	L2 — 8 Head In-Line Bosch Filler, time / pressure, 2 mL – 65 mL vials	•	•		
	L3 — 8 Head In-Line Bosch Filler, positive displacement ceramic pumps, 2 mL – 65 mL vials	•	•		
	Optima prefilled syringe and cartridge	•		•	•
Terminal sterilization	North – Pharmetics Water Shower Sterilizer	•			
Lyophilization	L2 — (2) 28sqm BOC Edwards, liquid Nitrogen; (1) 25sqm Hull, compressor		•		
	L3 — (3) 28sqm BOC Edwards, liquid Nitrogen		•		
Capping	L1 — Bosch 8 Head Rotary Capper	•	•		
	L2 and L3 — Bosch 10 Head Rotary Capper	•	•		
Inspection	Manual vial inspection	•	•		
	Automated vial and PFS inspection — Eisai and Seidenader	•		•	
Packaging	Vial coding (Video Jet)	•	•		
	Vial labeling (Accraply and Avery Labeler)	•	•		
	Cartoning (Jones Cartoner and Bosch)	•	•		
	Tray packing (Minnesota Tray Packer and Brooks)	•	•		
	Bundling (Kiener Stretch Bundler and Oliver Shrink Tunnel)	•	•		
	Banding (Axon Bander)	•	•		
	Carton security labeler (Shorewood Labeler)	•	•		
	Manual packaging processes	•	•		
	Leak testing (Densok and Techno)	•	•		
	Thermoforming (Bosch)	•	•		
Optel equipment for packaging serialization	•	•			

Greenville NC key equipment list—sterile dose development scale:

Equipment (features / scale)		Liquid vials	Lyophilized vials	Prefilled syringes	Cartridges
Compounding (PDS Suites 1 & 2)	Disposable flexible containers (up to 200L) — Sartorius disposable systems with LevMixer® technology	•	•		
	Magnetic stirrers	•	•		
	Benchtop mixers	•	•		
	Disposable technology for Phases I, to III CTM	•	•		
Vial washing	Cozzoli vial washer (PDS Suite 1)	•	•		
	Bosch integrated rotary washer (PDS Suite 2)	•	•		
Depyrogenation	Despatch depyrogenation oven (PDS Suite 1)	•	•		
	Bosch depyrogenation oven (PDS Suite 2)	•	•		
Component sterilization and drying (PDS Suites 1 & 2)	Stoppers — RTS or RTU steam autoclave	•	•		
Filling and stoppering	Flexicon FP50, single head filler. 2 mL – 50 mL vials (PDS Suite 1)	•	•		
	Bosch MLF 3020 integrated vial filling line 2 headed filler ISO 2R – 20R vials (PDS Suite 2)	•	•		
Terminal sterilization	Pharmetics steam autoclave	•			
Lyophilization	VirTis Lyophilizer — 24 sqft / 2.2 m ² (PDS Suite 1)		•		
	2 x IMA. Lyomax 7 — 75sqft / 7 m ² (PDS Suite 2)		•		
Capping	FP50 integrated crimping station (PDS Suite 1)	•	•		
	Bosch VRT 1020 integrated capper (PDS Suite 2)	•	•		
Inspection & packaging (PDS Suites 1 & 2)	Manual vial inspection	•	•		
	Vial packaging	•	•		
	Carton security labeler (Shorewood Labeler)	•	•		
	Manual packaging processes	•	•		

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* Commercial scale development batches are manufactured on commercial equipment.

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

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