

FACILITY FACTS:

Development and Commercial Workforce: 200+

CDMO Footprint: 120,000 square feet

Regulatory Approval: U.S. FDA, U.S. DEA, and Foreign Health Ministries – Danish Inspectorate, Anvisa (Brazil), and Turkish MOH

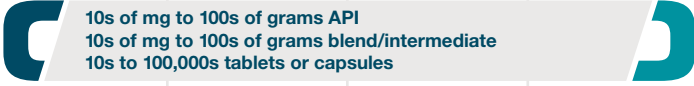

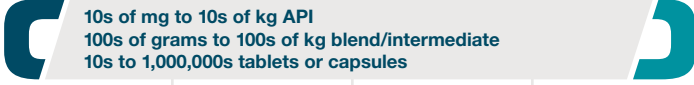
Potency Capability: Up to Category 3B

DEA Controlled Substance Registrations:

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

Specializations: Modified release technology, phase-appropriate formulation and analytical development, complex formulations, controlled substances, high potency compounds

Capabilities – Concept Through Commercialization			
Formulation & Process Development	Analytical	Quality Assurance & Regulatory Compliance	Manufacturing & Packaging
Physicochemical characterization	Raw material release	Assistance with end-to-end filing strategies	Clinical through commercial
Excipient compatibility	In-process testing	Early stage regulatory guidance	Single/multilayer tablets
Dosage form design	Finished product release testing	Late phase/NDA consultation	API in capsules/bottles
Solubility assessment	Cleaning method development	Preparation of regulatory documentation	Powder blend/multiparticulate capsules
Process design & optimization	Method development, verification, & validation	eCTD submission ready	Functional/non-functional film coating
Scale-up & technology transfer	ICH stability & photostability	FDA meeting support	Packaging – serialized bottles

Product Life Cycle – Scale & Capacity							
R&D	Preclinical	GLP Tox	Phase I	Phase IIa	Phase IIb	Phase III	Commercial
 <p>10s of mg to 100s of grams API 10s of mg to 100s of grams blend/intermediate 10s to 100,000s tablets or capsules</p>							
 <p>10s of mg to 1 kg API 100s of grams to 15 kg blend/intermediate 10s to 100,000s tablets or capsules</p>							
 <p>10s of mg to 10s of kg API 100s of grams to 100s of kg blend/intermediate 10s to 1,000,000s tablets or capsules</p>							

Quantities depend on equipment capacities and site of project execution.

Analytical Equipment			
Category	Equipment Description	cGMP QC	Analytical Development
Chromatography	No Chromophore – Thermo Scientific Corona Veo Rapid Separation Charged Aerosol Detector		●
	UPLC – Waters Single Quadrupole Detector (SQD)		●
	UPLC – Waters Acquity H-Class with QDa		●
	UPLC – Waters Acquity H-Class (Quaternary)		●
	UPLC – Waters Acquity I-Class (Binary)		●
	UPLC – Waters Acquity H-Class	●	●
	UPLC – Waters Acquity TUV Detectors	●	●
	UPLC – Waters Acquity PDA Detectors	●	●
	HPLC – Agilent 1260		●
	HPLC – Waters Acquity QDa (LC-MS)		●
	HPLC – Waters 2695 Alliance	●	
	HPLC – Waters 2487/2489 Dual Absorbance UV Detectors	●	
	GC – Agilent 6890	●	
	GC – Agilent 7890B	●	●
	GC – Agilent AG1888 Headspace Sampler	●	
	GC – Agilent 7697A Headspace Sampler	●	
Spectroscopy	FT-IR – Perkin Elmer Spectrum One	●	
	FT-IR – Alpha II		●
	Agilent Cary 60 UV-Vis		●
	Agilent 8453 UV-Visible Spectrophotometer	●	
Lab Automation	Automated Sample Preparation System – Hanson Research Vision AutoPlus	●	
	Automated Sample Preparation System – Sotax Tablet Processing Workstation (TPW)		●
Dissolution Systems	Distek 2500	●	●
	Hanson Research Vision Elite 8	●	●
	Automated Dissolution – Agilent 8453 UV-Visible Spectrophotometer (Chemstation)	●	
	Agilent 708 DS		●
	Fully Automated Dissolution System with Online UV – Sotax AT MD		●
Particle Size Analysis	Horiba Camsizer		●
	Microtrac S3500		●
	Malvern 3000 Mastersizer (Dry & Wet)		●
Moisture Analysis	Karl Fisher (Volumetric and Coulometric) MT-V30S/MT-T70	●	●
Other Characterization	Total Organic Carbon (TOC) – Sievers M9	●	●
	Polarimetry – Anton Paar MCP 150	●	
	Refractive Index - Anton Paar Abbemat 350	●	
	Friability – ERWEKA TAR 120		●
	Hardness – Sotax HT100 and AT4		●
	Disintegration – Distek 3100		●
	Viscosity – Brookfield DV1	●	
	Density – Anton Paar DMA 4500	●	
	Differential Scanning Calorimetry (TA DSC2500)		●
	Thermal Gravimetric Analysis (TA TGA5500)		●
	Mettler Toledo pH/Conductivity Meter		●
	Rudolph Autopol 5 Plus Polarimeter		●
	Chambers	Bahson Stability Chambers	
BMT Climacell EVO Stability Chamber (Photostability)			●
Atlas Suntest			●

Process Equipment					
Category	Model & Equipment Type	Manufacturer	Scale	Development	Commercial
Blending	Labmaster V-Blender	Patterson-Kelley	4 qt, 8 qt, 16 qt	●	
	Labmaster Bin Blender	Patterson-Kelley	4 qt, 8 qt, 16 qt	●	
	MaxiBlend 1-2-3 Bin Blender	GlobePharma	1 ft³, 2 ft³, and 3 ft³	●	
	Maxi-Tumbler Bin Blender	Ima	30 L, 100 L, 325 L, 700L	●	●
Bead Manufacturing, Granulation, and Coating	Fluid Bed	Freund-Vector	40 mL – 1200 mL	●	
	VFC-LAB 3 FLO-COATER® Fluid Bed System (with GRANUREX® GXR-35)	Freund-Vector	2 L – 14 L	●	
	FLM1 Fluid Bed	Freund-Vector	1 L – 4 L	●	
	GPCG-3 Fluid Bed Coater	Glatt	5 L, 10 L, 7" Wurster	●	
	GPCG-30 Fluid Bed Coater	Glatt	100 L, 18" Wurster	●	●
	GPCG-120 Fluid Bed Coater	Glatt	420 L, 32" Wurster		●
	Granurex GX-40	Freund-Vector	1 kg – 6 kg	●	
	Granurex GX-125	Freund-Vector	30 kg – 200 kg		●
	MG-55 Lab Extruder	LCI	15 kg – 20 kg/hr	●	
	Marumerizer; Spheronizer	LCI	1 L Working Volume	●	
	TFC-Lab Micro Roller Compactor	Freund-Vector	5 g – 1 kg/hr	●	
	WP 120 Roller Compactor	Alexanderwerk	5 g – 40 kg/hr	●	
	WP 200 Roller Compactor	Alexanderwerk	Up to 400 kg/hr		●
	GMXB-Pilot High Shear Granulator	Freund-Vector	10 L, 25 L, and 65 L	●	●
	GMX-Lab Micro High Shear Granulator	Freund-Vector	1 L and 4 L	●	
	Milling	Comil U3	Quadro	From 100 g	●
Comil 197AS		Quadro	Up to 360 kg/hr	●	●
Fitzmill L1A		Fitzpatrick	5 g – 50 kg/hr	●	
Fitzmill M5A		Fitzpatrick	100 kg – 500 kg/hr	●	
Fitzmill D6A		Fitzpatrick	200 kg – 1,000 kg/hr		●
Delta-Vita Wet Media Mill		Netsch	35 mL - 2 L	●	
Compression	RD10A	Natoli	Single Station	●	
	RD30	Natoli	60,000 tablets/hr	●	
	Model C	Carver	Single Station	●	
	Piccola	Riva	24,000 tablets/hr	●	
	XL100 Pro	Korsch	86,400 tablets/hr	●	
	FE-55	Fette	432,000 tablets/hr		●
Tablet Coating	LDSCS-5 Tablet Coater	Freund-Vector	0.5 L – 8.0 L	●	
	BTC-100 Tablet Coater	L.B. Bohle	25 L – 160 L	●	●
Powder Filling	Profiller 3700	Torpac	1k – 14k capsules/hr	●	
	AccoFil	M&O Perry	2 mg – 1000 g	●	
	Quantos Powder Dosing	Mettler Toledo	1 mg – several grams	●	
Oven Drying	Tray Drying Ovens	Casburt	80-Tray Capacity		●
	Tray Drying Ovens	Gruenberg	80-Tray Capacity		●
Encapsulation	GKF 400	Bosch	19,000 capsules/hr	●	
	Futura	MG America	96,000 capsules/hr	●	●
	Suprema	MG America	50,000 capsules/hr	●	●
Packaging	Bottle Packaging Line	Various	40 cc – 500 cc	●	●