



Development and Clinical Trial Material Manufacturing

SUMMARY OF CAPABILITIES

BioDuro-Sundia's Pharmaceuticals team is well versed in turning challenging molecules to dosage forms ready for clinical trial in an efficient, reliable, and timely manner.

A highly skilled manufacturing team combined with knowledgeable formulation scientists and supported by experienced analytical development group enable seamless early phase drug product development and CTM batch manufacturing. Mobile processing equipment, flexible suites combined with compliance oversight from an experienced QA department reflect our commitment to excellence in performance and the highest standards of quality.

Potency Capability: OHC 3 out of 4 (OEL: 0.03 ug/m³ - 10 ug/m³)
 Number of Employees: 80+

ADDRESS:

9601 Jeronimo Road, Irvine, CA

FACILITY CAPABILITY HIGHLIGHTS:

- Single-Layer and Bilayer Tableting
- Multi-Particulate Systems
- Controlled and Sustained Release
- High Shear Granulation
- Dry Granulation
- Spray Granulation
- Precision Coating
- Functional Coating
- Spray Drying
- Hot Melt Extrusion
- Amorphous Solid Dispersion ASDs
- Multi-Dose Capsule Filling
- API – Polymer Bead Layering

MANUFACTURING CAPABILITIES: DEVELOPMENT & CLINICAL TRIAL SUPPLY

Tablets/Capsules	Particle Engineering	Other
Immediate Release Tablets	Milling	Coated Pellets and Beads
Mini Tablets	Solid and Fluid Micronization	Controlled Release Beads
Sustained Release/ Controlled Release Tablet	Spray Drying	Taste-Masking and Taste Evaluation
Bilayer Tablets	Hot Melt Extrusion	Wet Granulation
Matrix Tablets	Screening and Delumping	Roller Compaction and Slugging
API in Capsules	Extrusion and Spherization	Fluid Bed Granulation
Blend in Capsules	Lyophilization	Pan Coating
Pellets or Beads in Capsules	Rotavap	Fluid Bed Coating

PRODUCT LIFE CYCLE BY DOSAGE FORM:

	Early Stage			Late Stage		Commercial	
	Formulation Development	Analytical Development	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer
Tablet / Capsule	•	•	•	•	•		
Powder / Granules	•	•	•	•	•		

FULL SCOPE OF AVAILABLE MACHINERY:

	Equipment/Scale	Capsules	Powders	Tablets	Mini Tablets
Spray Drying	Buchi B-290 • 150 ml/hr solvent evaporation Anhydro MS35 • 2 kg/hr solvent evaporation Anhydro MS150 • 10 kg/hr solvent evaporation		• • •		
Drying	Precision Vacuum Oven Solvent Rated Vacuum Oven Lindberg Solvent Rated Convection Oven Gruenberg Solvent Rated Convection Oven		• • • •		
Hot Melt Extrusion	Haake Mini Lab II Micro Compounder • 10 grams Leistritz Nano 16, 16mm • 0.3 kg/hr Leistritz ZSE-18, 18mm • 3kg/hr		• • •		
Tablet Compression	Globe Pharma Manual Tablet Press Minipress Single Station Tablet Press Korsch XL-100 Single-Sided Rotary Press • 20,000/hr Korsch XM12 Single/Bilayer Rotary Press • 32,000/hr Korsch XL-400 Single-Sided Rotary Press • 65,000/hr			• • • • •	• • • • •
Encapsulation	Xcelodose 600 • 150/hr Profill 1100 • 600/hr InCap • 1,000/hr Planeta 50 • 3,000-50,000/hr ACG-PAM AF90T Capsule Filler • 4,000/hr	• • • •	• • • •		•
Particle Size Reduction	Hosokawa 50 AS Spiral Jet Mill • 0.3 kg/hr L1A Fitzmill • 7 kg/hr DASO-6 Fitzmill • 100 kg/hr Quadro Comil 197 • 360 kg/hr		• • • •		
Weight Sorter	SADE SP-140 • 2,000 – 4,000 units/hr SADE SP-200 • 4,000 – 6,000 units/hr	• •		• •	• •
Pan Coating	O'Hara M5 coater Freund Vector LDCS Hi-Coater • 0.5, 1.5, 6, 8 L Freund Vector LDCS Pilot Hi-Coater • 20, 55 L	• • •		• • •	• • •
Blending and Granulation	Freund Vector TFC Lab Micro Huttlin Mycromix High Shear Granulator Freund Vector GMX Lab Micro/GMX-25 High Shear • 1, 4, 25 L Bohle LM40 Bin Blender • 5, 10, 20, 40 L Gerteis Mini-Pactor • 10kg/hr Bohle PTM300 Bin Blender • 50, 100, 300 L		• • • • • •		
Fluid Bed Processing	Freund Vector VFC-LAB Micro • 600 g Huttlin Solid-lab 1 Glatt GPCG2 Fluid Bed • 3, 12 L		• • •		• • •
Packaging	LM3905-01 Induction Sealer • 500 bottles/day Electronic Torque Tester • 500 bottles/day CVC-SC202 Tablet/Capsule Bottle Filler • 500 bottles/day	• • •		• • •	
Stability chamber	Thermo Scientific Forma Environmental Chamber (5.0 C) Thermo Scientific (-80 to -20 C) Sanyo (-20 C) Environmental Specialties (30 to 40 C / 65-75%) Environmental Specialties / ES2000 (0 to 70 C / 60-75%)	• • • • •	• • • • •	• • • • •	• • • • •

ANALYTICAL EQUIPMENT:

Laboratory Capabilities	Instrumentation available	
Raw Material testing	HPLC	Dissolution Test Station w/Autosampler
Finished Product Testing	UPLC	USP III Dissolution
In-process Testing	Corona CAD (Detector)	Fiber Optic Detector
Method Development	UV/Vis, PDA (detector)	QC-21 Disintegration w/Autosampler
Method Validation	Reflective Index Detector	Karl Fischer Titrator
Method Transfer	Fluorescence Detector	Karl Fischer Titrator w/ oven sampler
ICH Storage and Stability Testing	6890 Gas Chromatograph	Electronic Tongues
Equipment Cleaning	G1888 GC Headspace sampler	Scanning Electron Microscope (SEM)
	Cary 60 UV-Vis- Spectrophotometer	FT4 Rheometer
	Cary 50 BIO UV-Vis- Spectrophotometer	Powder X-Ray Diffraction (pXRD)
	Spectrum 100 FTIR	Differential Scanning Calorimeter (DSC)
	Spectra Max M3 Microplate Reader	Malvern 3000 Particle Size Analyzer with Hydro SV

CONTACT US TODAY TO DISCUSS YOUR NEEDS!

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