



Drug Product: Commercial

The BioDuro-Sundia Advantage

- Top 3 manufacturer in North America for amorphous solid dispersion OSDs
- Technology transfer and process validation (QbD, process scale-up)
- High capacity for OSD manufacturing (tablets, capsules): >2 billion units
- Turnkey commercial solutions: SDD, HME, fluid bed, pan coating, tablets, capsules
- Integrated analytical support from development through commercial production
- Recent and relevant GMP audit history with 100% recommendation for qualification (FDA, QP, Clients)

15+
Commercial
Products

Manufacturing Capabilities: Commercial Production

Tablets

- Immediate Release Tablets
- Coated Tablets
- Matrix Tablets

Capsules

- API in Capsules
- Blend in Capsules
- Pellets in Capsules
- Tablets in Capsules
- Capsules in Capsules
- Softgels in Capsules

Other

- Coated Pellets, Coated Beads
- Controlled Release Beads

Related Capabilities

Particle Size Reduction

- Milling
- Micronization

Amorphous Dispersions

- Spray Drying
- Hot Melt Extrusion

Granulation

- Wet Granulation
- Roller Compaction
- Fluid Bed Granulation

Coating

- Pan Coating
- Fluid Bed Coating



Equipment

Manufacturer

Capacity

Spray Drying	<ul style="list-style-type: none"> • PHARMASD PSD-4 	<ul style="list-style-type: none"> • GEA 	<ul style="list-style-type: none"> • 70 kg solution/hr
Post Drying	<ul style="list-style-type: none"> • LBB2-27 Forced Convection Oven • Solvent Rated 200K Tray Drying Oven 	<ul style="list-style-type: none"> • Despatch • O'Hara 	<ul style="list-style-type: none"> • 270 kg • 200 kg
Hot Melt Extrusion	<ul style="list-style-type: none"> • ZSE-27, 27mm 	<ul style="list-style-type: none"> • Leistritz 	<ul style="list-style-type: none"> • 25 kg/hr
Tablet Compression	<ul style="list-style-type: none"> • PT3090 Tablet Press • NP-255 Tablet Press • XL-400 Tablet Press 	<ul style="list-style-type: none"> • Fette • Natoli • Korsch 	<ul style="list-style-type: none"> • 92,000 tablets/hr • 42,000 tablets/hr • 52,000 tablets/hr
Encapsulation	<ul style="list-style-type: none"> • ACG-PAM AF90T Capsule Filler • Planeta 50 	<ul style="list-style-type: none"> • ACG • MG 	<ul style="list-style-type: none"> • 90,000 capsules/hr • 6,000-50,000 capsules/hr
Sifting	<ul style="list-style-type: none"> • FlexSift S10 	<ul style="list-style-type: none"> • Quadro 	<ul style="list-style-type: none"> • 300 kg/hr
Particle Size Reduction	<ul style="list-style-type: none"> • Quadro Comil 194 • Fitzmill (x4 units) 	<ul style="list-style-type: none"> • Quadro • Fitzpatrick 	<ul style="list-style-type: none"> • 1,750 kg/hr • 100-500 kg/hr
Weight Sorter	<ul style="list-style-type: none"> • SADE SP-240 Floor Standing Tablet/Capsule Weight Sorter 	<ul style="list-style-type: none"> • Precision 	<ul style="list-style-type: none"> • 9,000 units/hr
Coating	<ul style="list-style-type: none"> • Accela Cota 60" • Accela Cota 60" (w/ dewpoint control) 	<ul style="list-style-type: none"> • Thomas Engineering • Thomas Engineering 	<ul style="list-style-type: none"> • 120 kg • 120 kg
Blending and Granulation(wet/dry)	<ul style="list-style-type: none"> • TFC-220 Roller Compactor • PM-600 Blender • GMA-400 High Shear Granulator 	<ul style="list-style-type: none"> • Freund-Vector • Bohle • Bohle 	<ul style="list-style-type: none"> • 1-30 kg/hr • 200, 400, 600, 800 L • 120-320 L
Fluid Bed Processing	<ul style="list-style-type: none"> • HDGC-200 Fluid Bed • HDGC-600 Fluid Bed 	<ul style="list-style-type: none"> • Hüttlin • Hüttlin 	<ul style="list-style-type: none"> • 100-527 L • 1,315 L



Commercial Spray Dryer: PSD-4



Commercial Hot Melt Extruder: ZSE-27