



# Oral solid dose development and manufacturing facility

## Bourgoin, France

### Facility facts

**Experience:** Pharmaceutical activities for 60+ years, including 10+ years in development

**Services workforce:** ~160

**Number of employees:** Approx. 600 employees

**Regulatory approval:** FDA, ANSM/EMA, KFDA, GISK, ANVISA, PMDA

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### Overview

Our Bourgoin facility is an FDA-approved center of excellence for early- and late-stage development and commercial supply of oral solid dose (OSD) products with a specialization in high potency APIs.

The facility includes a new 430 sq. m. dedicated research and development hub offering state-of-the-art equipment and technologies to support formulation development and mature product characterization of OSD forms.

We serve worldwide markets, including Asia, with automatic visual inspection for tablets and capsules, and small-scale commercial supply for orphan/niche indications.

The Bourgoin facility is also a center of excellence for packaging in Europe, including sachets, bottling (with nitrogen blanketing), and late-stage customization capabilities to address niche markets, serialization, and aggregation.

### Capabilities

- **Early development of oral solid dose** (from 100 g batch size)
- **Small-scale and large-scale development and commercial GMP manufacturing** (2 kg to 800 kg)
- **Specialized in handling highly potent APIs** up to 3B category, including selective cytostatic APIs
- **Packaging** (bottles, blisters, high-speed lines, and late-stage customization)
- **OSD forms:** Tablets, capsules, powder, and granules
- **Non-sterile liquids**

# Key equipment list

## GMP capabilities for development and commercial

Equipment (features/scale)		Powders and granules	Tablets and mini-tablets	Capsules (powder and pellets)	Non-sterile liquids	High potency
Blending	Torpac ProMixer 10 L	✓				✓
	Buck valve MC 10 high containment valve 10 L to 1,500 L tote bins, GEA IBC blenders	✓	✓	✓		✓
Wet granulation, milling, and drying	Glatt HSG TMG, multiple bowls 0.5 L to 8 L Midi Glatt TMG FBD, conventional drying, Wurster column	✓				✓
	GEA HSM 30 L, GEA FBD MP2 65 L, Quadro Comil U10, top and bottom spray, pellet and mini-tab coating	✓				✓
	GEA MP2 advanced, Comil U10, top spray	✓				
	GEA HSM 300L, GEA FBD 300L, Quadro Comil U20, top spray	✓				✓
	Comil U5	✓				✓
	Comil 194	✓				✓
	High Shear Diosna P 400 L	✓				
	Glatt Combo 450	✓				
	GEA High Shear Fielder PMA 800 L	✓				✓
	Aeromatic Fielder Sirocco 600 L, fluid bed dryer	✓				✓
Dry granulation—roller compaction	Oven drying/SAT ovens Glatt GSE 200	✓				
	Gerteis Mini Pactor and Quadro Comil U10, gravity feeding	✓				✓
	Gerteis Mini Pactor, vacuum transfer	✓				
Compression	Gerteis Macro Pactor, gravity feeding	✓				✓
	Korsch XL 100 WIP		✓			✓
	IMA Synthesis 500 WIP		✓			✓
	IMA Comprima 300		✓			
	Synthesis 500 (bi-layer)		✓			
	Synthesis 330		✓			✓
Coating	Korsch XL400		✓			
	Freund Vector LCDS Hi coater system (0.5 L, 4 L, 8 L pans), aqueous and organic solvent		✓			✓
	IMA Perfima Lab (6 L, 10 L, 30 L, and 70 L pans), aqueous and organic solvent		✓			✓
	IMA Perfima Lab 30 L and 70 L		✓			
	IMA Perfima 200 L		✓			
	IMA Perfima 500 L		✓			✓
	Driam DRC 1600		✓			

## Key equipment list

### GMP capabilities for development and commercial (continued)

Equipment (features/scale)	Powders and granules	Tablets and mini-tablets	Capsules (powder and pellets)	Non-sterile liquids	High potency
Encapsulation and weight sorting	Manual encapsulator Torpac Profiller 1100 and 3300			✓	✓
	Syntegon GKF60 - microdosing (neat API) or powder blend fill			✓	✓
	Check weigher SADE		✓	✓	
	IMA Zanasi THC48 for encapsulation and IMA Precisa weight sorting in line			✓	✓
	MGII-MG37 (powder only)			✓	
	Bosch GKF 1500			✓	
	Precisa Weight Sorter 120			✓	
Visual inspection	IMA Sensum Spine		✓	✓	✓
Sachet filling	Volpak 140P, single and twins	✓			
Liquid filling	10 L to 10,000 L, solutions/suspensions sprays			✓	✓
	Filling into plastic, glass bottles, or aluminum cans			✓	✓
Packaging: Stability and primary clinical packaging	Bottles	✓	✓	✓	✓
	High-speed Marchesini blister lines (thermo form, cold form, online printing, N2 flushing, push through, peel, peel and push)				
	Small-scale blister line (SSCM, stability, blister POC)		✓	✓	✓
	Brite stock blister late-stage customization line (for small order quantity)				
Primary, secondary, and tertiary	Wallets and child-resistant blister cards				
Serialization/aggregation					

# Key equipment list

## R&D capabilities for development

Equipment (features/scale)		Powders and granules	Tablets and mini-tablets	Capsules	Non-sterile liquids	High potency
Blending	Erweka AR402 (1 L, 2 L, 3.5 L, 8 L), diffusion mixing, rotating	✓				✓
	Torpac ProMixer (2 L, 3 L, 5 L, 10 L)	✓				✓
	Turbula with SS containers 5 L and 10 L	✓				✓
Dry milling	Erweka FSG2, oscillating bar	✓				✓
	Frewitt TC-Lab, 500 µm to 3,000 µm, conical	✓				✓
	Glatt GSE 80, Rotor sieve 1.1 mm, 1.3 mm, and 2.0 mm, conical	✓				✓
Wet granulation—top and bottom spray	Glatt TMG high shear mixer granulator (0.5 L, 1 L, 2 L, 4 L, 6 L, 8 L), solvent capable	✓				✓
	Glatt Midi fluid bed dryer, granulator, and coater, 3 L vessel, solvent capable	✓				✓
Dry granulation and roller compaction	Styl'One Evo, one punch, compaction simulator with Gerteis hand mill	✓				✓
	Freund Vector TFC-LAB Micro	✓				✓
Compression	Styl'One Evo, mono-punch tablet press and compression simulator		✓			✓
	Riva Piccola, 10 stations, mini-tabs capable		✓			✓
Coating	Glatt GC1 0.8 L, solvent capable		✓			✓
Encapsulation	Manual encapsulator, Torpac Profiller 1100			✓		✓
	Manual powder filler, Perry Accofil 4400 (used for vacuumetric dosing into capsule, sachet, or bottle)			✓		✓
	Xcelodose XD600, neat API into capsule, 100% weight control			✓		✓
Sorting	Weight sorter SD SP-B40 benchtop		✓	✓		
Non-sterile liquid preparation	IKA Synthesis Reactor, 5 L vessel				✓	✓
Packaging	SEPHA EZ blistering with modified atmospheric packaging option		✓	✓		✓
	Manual bottling, induction thermoforming		✓	✓		✓
Characterization	Malvern 3000 for particle size distribution	✓				✓
	FT4 for powder rheometry	✓				✓
	Geopyc, Accupyc	✓				✓
	XRPD D2 Phaser from Bruker	✓				✓
	DSC 3+ from Mettler Toledo	✓				✓
	Scanning electron microscope (SEM), Phenom ProX Génération 5	✓				✓
	Polarized light microscope, Olympus BX51	✓				✓
	Mechanical properties by compaction simulation (Styl'One)	✓				✓
Spray drying	Buchi Mini Spray Dryer B-290 Advanced + Inert Loop B-295	✓				✓
Specific stability studies	ASAP Prime	✓	✓	✓		✓

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