

# Summary of capabilities

## Bourgoin, France

### Oral solid dose development and manufacturing facilities

**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-square-meter dedicated research and development hub offering state-of-the-art equipment and technologies to support formulation development and mature product characterization of oral solid dose 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.

Facility facts:		Capabilities:
Facility facts:	History: Pharmaceutical activities for 60+ years, including 10+ years in development	<ul style="list-style-type: none"> <li>• Early development of oral solid dose (from 100g batch size)</li> <li>• Small-scale and large-scale development and commercial GMP manufacturing (2kg to 800kg)</li> <li>• Specialized in handling highly potent APIs up to 3B category, including selective cytostatic</li> <li>• Packaging (bottles, blisters, high-speed lines, and late-stage customization)</li> <li>• OSD forms: tablets, capsules, powder, and granules</li> <li>• Non-sterile liquids</li> </ul>
Services workforce:	~160	
Employees at the site:	Approx. 600 employees	
Regulatory approval:	FDA, ANSM/EMA, KFDA, GISK, ANVISA, PMDA	
Potency capability:	Up to 3B category (eq. OEL 10ng/m3)	
Contact info:	40 Boulevard de Champaret CS 11006 38307 Bourgoin Jallieu Cedex, France	
	Tel: +33 4 7493 8700 Fax: +33 4 7493 8781	

# Summary of capabilities

## Bourgoin 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	Buck valve MC 10 high containment valve 10L to 1,500L tote bins - GEA IBC blenders	•	•	•		•
	Torpac Promixer 10L	•	•	•		•
Wet granulation, milling, and drying	Glatt HSG TMG - Multiple bowls 0,5 to 8L Midi-Glatt TMG FBD Conventional drying - Wurster column	•				•
	GEA HSM 30L - GEA FBD MP2 65L - 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	•				•
	GEA Sirocco D600	•				•
	COMIL US (mobile) - powders, granules and high potency	•				•
	Comil 194	•				•
	High shear Diosna P 400L	•				
	Glatt combo 450	•				
	GEA high shear fielder PMA 800L	•				•
	Fluid bed dryer (aeromatic fielder)	•				•
	Oven drying/SAT ovens glatt GSE 200	•				
Dry granulation/roller compaction	Gerteis mini pactor and quadro comil U10 - gravity feeding	•				•
	Gerteis mini pactor - vacuum transfer	•				
Compression	Korsch XL 100 WIP		•			•
	IMA synthesis 500 WIP		•			•
	IMA comprima 300		•			
	Synthesis 500 (bi-layer)		•			
	Synthesis 330		•			•
Korsch XL400		•				
Coating	Freund Vector LCDS Hi Coater System (0.5L, 4L, 8L pans) - aqueous and organic solvent		•	•		•
	IMA Perfima Lab (6L, 10L, 30L, and 70L pans) -aqueous and organic solvent		•			•
	IMA Perfima Lab 30L and 70L		•			
	IMA Perfima 200		•			
	IMA Perfima 500		•			•
Driam DRC 1,600		•				

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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			•		•
	Xcelodose® XD600S - neat API into capsules - 100% weight control			•		•
	Syntegon GKF60 - microdosing 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 to 10,000 liters - solutions/suspensions/sprays				•	•
	Filling into plastic, glass bottles, or aluminium cans				•	•
Packaging stability and primary clinical packaging  Primary, secondary, and tertiary commercial packaging inc. serialization/aggregation	Bottles	•	•	•		•
	Blisters (thermo form and cold form) Brite stock blisters - late-stage customization - wallets		•	•		•

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## Bourgoin key equipment list – R&D capabilities for development

Equipment (features/scale)		Powders and granules	Tablets	Capsules	Non-sterile liquids	High potency (3B)
Blending	Erweka AR402 (1L, 2L, 3.5L, 8L) - diffusion mixing - rotating	•				•
	Torpac ProMixer - 2L, 3L, 5L, and 10L	•				
	Turbula with SS containers 5L and 10L	•				•
Dry milling	Erweka FSG2 - oscillating bar	•				•
	Frewitt TC-Lab - 500µm to 3,000µm - conical	•				•
	Glatt GSE 80 - Rotor sieve 1.1mm, 1.3mm, and 2.0mm - conical	•				•
Wet granulation top and bottom spray	Glatt TMG high shear mixer granulator (1-2-4-6-8L) - solvent capable	•				•
	Midi-Glatt fluid bed dryer, granulator, and coater - 3L vessel solvent capable	•				•
Dry granulation/roller compaction	Styl'One Evo - one punch - compaction simulator with Gerteis hand mill	•	•			•
Compression	Styl'One Evo - mono punch tablet press and compression simulator	•	•			•
	Riva Piccola - 10 station - minitabs capable		•			•
Coating	Glatt GC1 0.8L		•			•
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 - 5L vessel					
Packaging	SEPHA EZ blistering		•	•		•
	Manual bottling, induction thermoforming		•	•		•
Characterization	Malvern 3000 for particle size distribution	•				•
	FT4 for powder rheometry	•				•
	Geopyc, Accupyc	•				•
	XRPD - Bruker	•				•
	DSC 3+ (*Installation end of 2024)	•				•
	SEM (*Installation end of 2024)	•				•
	Polarized light microscope (*installation end of 2024)	•				•
	Mechanical properties by compaction simulation (Styl'One)	•				•
Specific stability studies	ASAP Prime®	•	•	•		•

\* For detailed equipment information, please contact your Thermo Fisher Scientific representative.

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



## Summary of capabilities

# From molecule to medicine: An integrated partner for every step in your drug development journey

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**Discover the power of partnership and our global network.**