

•• CARBOGEN AMCIS EXPANDS CAPACITY FOR PARENTERAL DRUG MANUFACTURING

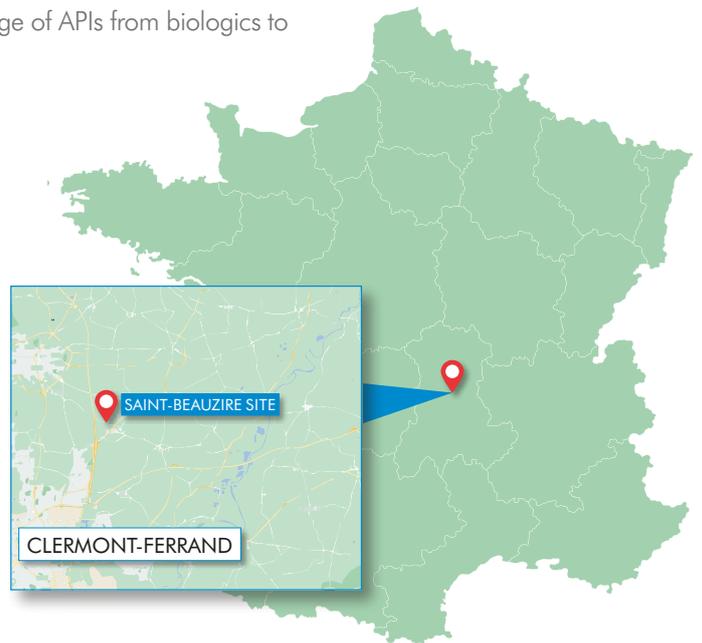
The newest state-of-the-art facility in France offers:

- Clinical and commercial supply, Annex 1 & GMP-compliant facility
- Larger capacities to supply customers with clinical batches for phase III clinical trials and small-scale for commercial
- Flexible formulation options, including liquid and lyophilised forms
- Ability to handle complex formulations, including a large range of APIs from biologics to highly potent compounds.
- This new site is situated in the city of Saint-Beauzire - North of Clermont-Ferrand in Auvergne, France.

•• FACILITY CAPABILITIES

The all-inclusive facility contains:

- 2 R&D Laboratories
- 2 Quality Control Laboratories: microbiology, physico & bio-chemistry
- Supports Services: Logistics, Utilities, Maintenance, Project management and administrative area
- 2 Manufacturing areas including formulation and aseptic filling



- Line 1: Liquid and lyophilised form - Vials

•• PRODUCTION LINE

	LINE 1 - LIQUID & LYOPHILISED	LINE 2 - LIQUID
FORMULATION	Up to 400 Litres tank	
ISOLATOR		
FILLING LINE		
LYOPHILISER		
BATCH SIZE	30k units of 2R – up to 45k	3.6k units per hour
FORMATS	Vials from 2 to 100R	Vials from 2 to 100R
API CATEGORIES	Full containment - From Cat 1 to Cat 4+	
SPECIAL FEATURES	Low temperature - Inert atmosphere - Viscous products - Aseptic formulation - Minimised losses	

•• DEVELOPMENT AND ANALYTICAL CAPABILITIES

Process Research & Development platform

- 2 Laboratories including: Isolator, Glovebox, Safety Cabinets
- 2 Lyophilisers, filling and capping machines for PR&D
- Analytical platform including HPLC and uPLC
- Storage chambers with different conditions for stress studies

Quality Control platform

- 2 Laboratories including: Fumehoods and Safety Cabinets
- HPLCs, uPLCs, LC-MS, Ion Chromatography
- Microbiological platform to perform Bioburden, Sterility and endotoxins tests
- Stability chambers for ICH stability studies