

# STERILE DRUG PRODUCTION FACILITY

An Advanced Hub for Parenteral Drug Manufacturing



CARBOGEN  
AMCIS

A Dishman Group Company

The Saint-Beauzire facility, operated by CARBOGEN AMCIS, is a cutting-edge drug production site located in Saint-Beauzire, north of Clermont-Ferrand in the Auvergne region of France.

This state-of-the-art facility plays a crucial role in developing and manufacturing parenteral drugs, offering a range of capabilities to meet the evolving needs of the pharmaceutical industry.

## FACILITY OVERVIEW

The Saint-Beauzire site is designed to support both clinical and small-scale commercial production, providing flexible solutions tailored to the demands of modern drug development. With capabilities spanning liquid and lyophilised drug formulations, the facility is equipped to handle a diverse range of active pharmaceutical ingredients (APIs), from biologics to highly potent compounds. This brand-new facility is GMP certified (successfully inspected by the ANSM in January 2025) and Annex 1 compliant.



## KEY FEATURES INCLUDE:

### •• PRODUCTION CAPABILITIES:

- Formulations in both liquid and lyophilised forms.
- Packaging options:  
**current:** vials  
**in future:** prefilled syringes (PFS) and cartridges
- Advanced containment measures for APIs across Categories 1 to 4+ (OELB).

### •• SPECIALISED ENVIRONMENTS:

- Low-temperature, inert-atmosphere and light sensitive solutions for complex formulations.
- Aseptic processes ensuring product integrity and safety.
- The lines are fitted with Grade A isolator technology with an in-line Lyophiliser for freeze-dried products.

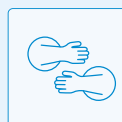
### •• BATCH FLEXIBILITY:

- Two advanced fully automated production lines under isolators tailored to meet different needs, ensuring versatility and quality in commercial drug supply and manufacturing:  
**Line 1:** for both liquid and lyophilized forms  
**Line 2:** for liquid forms in vials



## MANUFACTURING INFRASTRUCTURE

- The facility encompasses two state-of-the-art manufacturing areas dedicated to formulation and aseptic filling. The production lines are optimised for precision, minimised material loss, and the production of complex drug products.



### •• PRODUCTION LINE HIGHLIGHTS:

- Tanks with capacities up to 400 litres for formulation.
- Filling lines and lyophilisers for diverse product requirements.
- Fully integrated isolators for handling sensitive or potent APIs.

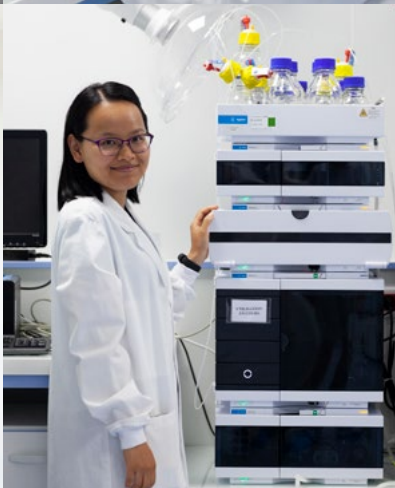
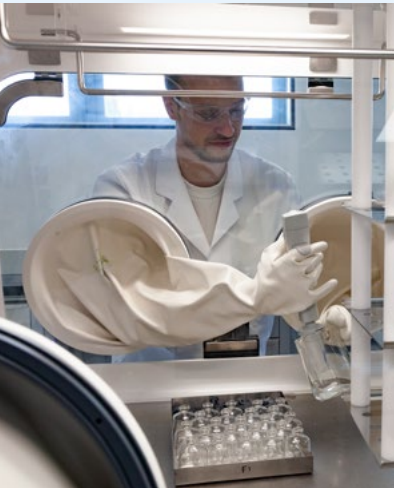
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## RESEARCH & DEVELOPMENT EXCELLENCE

- Research and development (R&D) is a cornerstone of the Saint-Beauzire site, with two advanced laboratories equipped to support innovative drug development and process optimisation. These labs are fitted with isolators, gloveboxes, and safety cabinets, ensuring safe and efficient handling of even the most complex formulations.
- To refine and optimise processes, the facility utilises specialised equipment such as lyophilisers, filling machines, and capping machines. Comprehensive analytical capabilities include tools like HPLC, uPLC, and storage chambers for stress testing. This robust setup enables a thorough evaluation of formulations, ensuring they meet both performance and stability criteria before scaling up to production.



## QUALITY ASSURANCE & CONTROL

- The Saint-Beauzire facility maintains rigorous quality standards with two specialised laboratories focused on microbiology, physico-, and biochemistry. These labs conduct critical testing to ensure product safety and compliance, including:
  - Bioburden analysis** to monitor microbial levels.
  - Sterility testing** to confirm aseptic conditions.
  - Endotoxin detection** for bacterial toxins.
- To support long-term stability assessments, the facility features stability chambers compliant with International Council for Harmonisation (ICH) guidelines. Additionally, advanced analytical tools, including:
  - HPLCs and uPLCs** for high-precision chromatography.
  - LC-MS** for mass spectrometry analysis.
  - Ion chromatography** for detailed chemical profiling.
- These resources ensure thorough and reliable analysis across every stage of production.

## COMPREHENSIVE SUPPORT SERVICES

- To ensure seamless operations, the facility integrates a range of support services, including logistics, maintenance, and project management, alongside a dedicated administrative team. This holistic approach ensures that clients receive high-quality solutions tailored to their needs.

## IN SUMMARY - FACILITY HIGHLIGHTS

The Saint-Beauzire facility is a key site for CARBOGEN AMCIS's pharmaceutical manufacturing operations. Its combination of advanced containment technologies, flexible production options, and the ability to handle complex drug formulations enables it to support both clinical development and small-scale commercial production. With comprehensive resources spanning research, manufacturing, and quality control, the facility is equipped to develop and produce specialised pharmaceutical products to meet diverse industry needs.

