

PRESS RELEASE

CARBOGEN AMCIS Secures GMP Certification After Successful ANSM Inspection for its Aseptic Drug Product Manufacturing Site

Bubendorf, Switzerland (March 24, 2025) – Switzerland-based CARBOGEN AMCIS, a leading pharmaceutical process development and Active Pharmaceutical Ingredient (API) manufacturing company, is pleased to announce the successful completion of the first inspection by the French regulatory authority, ANSM (Agence nationale de sécurité du médicament et des produits de santé), at its state-of-the-art sterile drug product manufacturing site in Saint-Beauzire, France.

The inspection, conducted from January, 20th to January, 24th, follows the site's opening in February 2023. This is the first inspection of a routine process by ANSM to ensure compliance with Good Manufacturing Practices (GMP). As a result, CARBOGEN AMCIS has been granted a GMP certificate for the Saint-Beauzire facility, marking a significant milestone in the site's successful start-up. The certificate allows for the manufacture and release of clinical and commercial sterile drug products. The site received authorization from the ANSM to manufacture, test and release drug products from February 2023 and since then has been working under this authorization with the first clinical batch released in January 2024.

"This achievement reflects our team's dedication and hard work" said Angie Stevens, Vice President, Drug Product Business Unit. "I am incredibly proud of the commitment and motivation every Saint-Beauzire employee shows. With this certification, we look forward to actively supporting our customers in bringing new drugs to market and shaping a bright future together."

A State-of-the-Art Facility

Opened in early 2023, the Saint-Beauzire facility represents a major investment by CARBOGEN AMCIS (60 million euros). It underscores the company's commitment to enhancing sterile drug product manufacturing capabilities. The 9,500m² site features two fully automated production lines for liquid and lyophilized drug products, supporting a wide range of therapeutic areas, including highly potent compounds and advanced therapies such as antibody-drug conjugates. The flexible and versatile setup is unique within Europe and fully compliant with the latest EU GMP Annex 1 standards for sterile medicinal products.

With over 15 years of expertise developing injectable and liquid pharmaceutical forms, CARBOGEN AMCIS' Saint-Beauzire site provides tailored solutions for pre-clinical and clinical trials and small-scale commercial manufacturing. It also creates significant job opportunities, employing approximately 130 highly skilled professionals

A Growing Portfolio of Services

“The successful ANSM inspection reaffirms CARBOGEN AMCIS as a reliable partner in the drug product manufacturing market,” said Helen Caddy-Leach, Head of Business Development, Drug Product. “With our extensive expertise and a state-of-the-art GMP-certified facility, we are well-positioned to support customers’ drug product projects with excellence.”

This new site complements CARBOGEN AMCIS’ existing capabilities as a renowned API manufacturer. “Having a cutting-edge facility dedicated to the development and manufacture sterile drug products, including to a commercial scale, strengthens our ability to offer comprehensive end-to-end services, from drug substance to drug product,” said Stephan Fritschi, CEO of CARBOGEN AMCIS. “This integrated approach is a significant advantage in today’s competitive pharmaceutical landscape and provides added value for our clients.”

Supporting Global Pharmaceutical Innovation

CARBOGEN AMCIS’ eight sites across Switzerland, France, the United Kingdom, China, and the Netherlands deliver cGMP-compliant, innovative technologies that enable pharmaceutical and biopharmaceutical companies to bring next-generation medicines to market. The Saint-Beauzire site completes the CARBOGEN AMCIS group portfolio and is integral to the company's production chain. The site plays a critical role in this mission by enhancing the group’s capacity to develop and manufacture advanced sterile drug products.

- To learn more about our GMP certified site, watch our dedicated video:
[CARBOGEN AMCIS Secures GMP Certification](#)

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CARBOGEN AMCIS (www.carbogen-amcis.com) is a leading service provider, offering a portfolio of drug development and commercialization services to the pharmaceutical and biopharmaceutical industry at all stages of drug development. The integrated services provide innovative chemistry solutions to support timely and safe drug development, allowing customers to make the best use of available resources. CARBOGEN AMCIS is a wholly owned subsidiary of Dishman Carbogen Amcis Limited., Ahmedabad, India

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