



BRINGING  
YOUR  
SCIENCE  
TO LIFE

Bioconjugation and  
Antibody Drug Conjugates



# Your Partner for Conjugation Projects



- **Pioneers in the highly potent landscape for over 14 years, we successfully managed numerous drug-linker projects. Since our first ADC project in 2005, many customers, ranging from small biotech to large pharmaceutical companies, expressed a growing interest in our ADC and bioconjugation abilities. We can manage projects from drug-linker to final drug product.**

CARBOGEN AMCIS offers tailored programs based on your needs and budget. You will benefit from our dedicated team of experienced chemists, biochemists and biologists, who can advise you on the best linker and conjugation strategy. For all other projects conducted by CARBOGEN AMCIS, safety and quality are central in the ADC area.

## Why choose us?



### Drug-linker

cGMP process development and manufacture of Warheads & Linkers (OEL < 0.01 µg/m<sup>3</sup>)



### Conjugation

cGMP Conjugation of mAb to Small



### Analytical

Outstanding analytical capabilities



### Clean Room

Clean Room fully qualified for cGMP manufacturing dedicated to bio-conjugation



### Purification

State of art purification technologies



### Dedicated Team

A multi-disciplinary and extensively experienced team



### Fill & Finish

Fill-&-Finish capabilities



### Support

Regulatory and CMC support



# Your Partner for Conjugation Projects



***“We advise our customers on the best conjugation strategy to successfully manage projects from drug-linker synthesis to final drug product manufacture.”***

**Luca** – Manager ADC

## Conjugation & Purification Capabilities

- Manipulation of biological molecules
- Chemical modification with linkers and activators
- Conjugation of monoclonal antibodies and biologics to small molecule compounds up to 20 L volume or ca.300g ADC per batch
- ÄKTA-Pure 25 chromatography system
- ÄKTA Ready Skid for large scale aseptic
- PALL SU-TFF up to 2.5m<sup>2</sup> automated system for aseptic diafiltration
- OEL 10 ng/m<sup>3</sup> 8h-TWA
- Aseptic environment with Grade D and C qualified areas
- cGMP compliant
- Single use liquid handling systems

## Analytical & Bioanalytical Capabilities

- In-process monitoring by various means such as: UV/Vis, HPLC, Endo-Safe, pH and conductivity
- ICH stability studies
- Full on-site analytical support for the release testing of the product
- Enzyme Linked Immunosorbent Assay (ELISA)
- SDS-PAGE (Gel Electrophoresis)
- iCE3 Imaged Capillary Isoelectric Focusing
- Bioanalyzer Agilent 2100
- Endotoxin analysis
- HPLC analysis (RP, SEC, HIC, PLRP)

## Fill & Finish Capabilities

In addition to our process research and manufacturing services for the fast supply of highly potent APIs, CARBOGEN AMCIS offers formulation services for highly potent drug products and cGMP aseptic production of parenteral drugs, including cytostatics and cytotoxics.

- Pre-clinical batches (for technical, stability or toxicology studies)
- Clinical batches (for phases I, II and III)
- Injectables: liquid and freeze-dried forms





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CARBOGEN AMCIS 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 also active in the marketing/sales and manufacture of Vitamin D analogues, Vitamin D, Cholesterol and Lanolin related products for key markets as pharmaceutical, cosmetic, food, feed as well as industry applications.

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