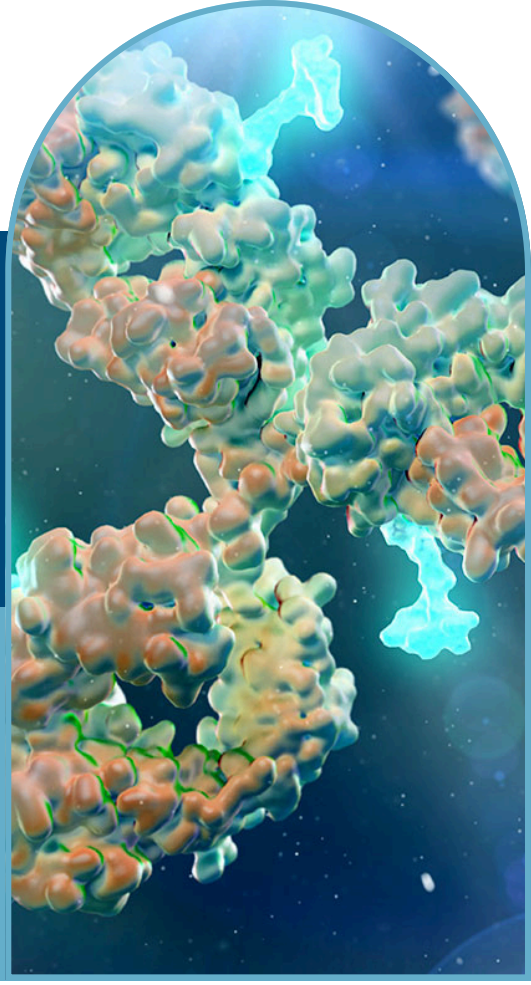
solvias



When Every Nanogram Matters:

THE CHALLENGE OF FREE PAYLOAD IN ANTIBODY-DRUG CONJUGATE DEVELOPMENT

A biotechnology company developing an antibody-drug conjugate (ADC) was preparing its program for clinical development and needed to establish a reliable method for monitoring free payload and payload-related impurities. The highly potent payload demanded both exceptional analytical sensitivity and specialized containment. Even trace amounts of unconjugated payload could impact product quality and patient safety, while safe analytical testing required dedicated facilities designed for highly potent compounds. To develop a sensitive, stability-indicating analytical method while ensuring safe handling of the compound, the company partnered with Solvias.

THE CHALLENGES

Free Payload Must Be Tightly Controlled
The therapeutic benefit of an ADC depends on the payload remaining attached to the antibody until it reaches the target cell. Even very low levels of unconjugated payload or payload-related impurities can affect product quality and patient safety, making their accurate quantification a critical requirement throughout development.

Extremely Potent Compounds Require Specialized Containment
The payload of this ADC had an occupational exposure limit (OEL) in the low nanogram-per-cubic-meter range. Developing analytical methods for these compounds requires laboratories specifically designed to safely handle highly potent materials while preventing cross-contamination and protecting laboratory personnel.

Sensitive and Stability-Indicating Methods Are Essential
Analytical methods must reliably distinguish intact ADC from free payload, degradation products, and related impurities while providing the sensitivity needed to detect trace-level species throughout product development and stability studies.

OUR COLLABORATIVE APPROACH

Sensitive HPLC Method Development
Solvias developed a stability-indicating HPLC method capable of separating free payload, payload-related impurities, and degradation products from the intact ADC. The method provided the sensitivity required to quantify trace levels of unconjugated payload throughout development. All analytical work was performed in Solvias' dedicated high-containment laboratory, designed to safely handle compounds with occupational exposure limits (OELs) as low as 5 ng/m³.

Phase-Appropriate Analytical Strategy
The method was designed to support evolving program needs, from early analytical characterization through qualification, validation, stability testing, and GMP release as the ADC advanced toward later-stage development. Analytical data were generated with regulatory expectations in mind, providing a robust foundation for CMC documentation and future product lifecycle management.

THE RESULTS

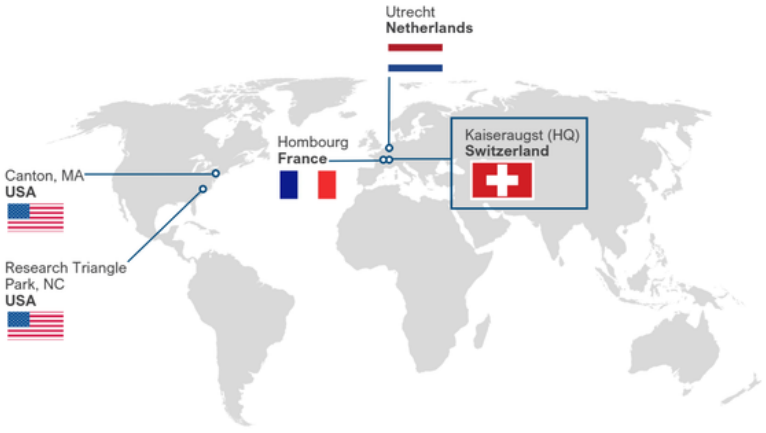
- Highly sensitive HPLC method developed for the quantification of free payload and payload-related impurities.
- Reliable separation of intact ADC, unconjugated payload, and degradation products through a stability-indicating analytical approach.
- Safe analytical handling of highly potent payloads in a dedicated high-containment laboratory supporting compounds with OELs as low as 5 ng/m³.
- Phase-appropriate analytical method supporting development, stability studies, and future GMP release testing.
- Regulatory-ready analytical package strengthening CMC documentation and supporting continued clinical development.

CONCLUSION

This case demonstrates how combining specialized high-containment facilities with expertise in HPLC method development enables reliable quantification of free payload and payload-related impurities. By providing a safe analytical environment together with stability-indicating methods, Solvias helped the customer generate high-quality data while advancing a complex ADC program toward clinical development.

WHY PARTNER WITH US?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m^2 of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



Contact us to speak with an expert: info@solvias.com

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