SAFC

Pharma & Biopharma Raw Material Solutions





- Our versatile maytansinoid products help accelerate your path to the clinic. Our offering includes:
- DM1 Mertansine: a GMP quality payload for your drug conjugate programs
- MAYCore[™] intermediate: an advanced payload intermediate that simplifies maytansinoid payload synthesis

Product features

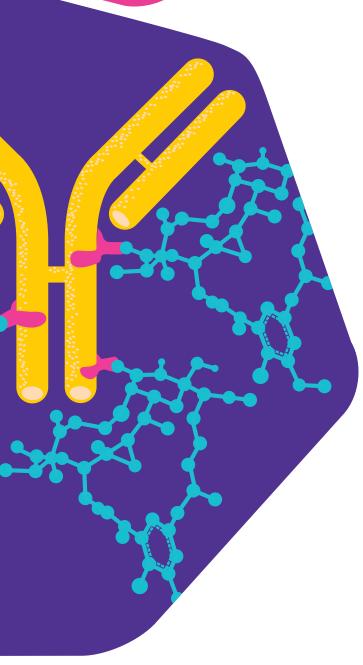
- · High purity material
- · Samples available free of charge
- MilliporeSigma DMF/ASMF for regulatory filings
- Suitable for up to phase I clinical studies with process validation to support path to commercial approval

Additional benefits

- Readily available stock to support your drug conjugation projects and accelerate your development timelines
- · Reduced supply chain risk and complexity
- Free licensing agreements and no royalty payments
- Call on our global network of scientists, engineers, regulatory experts, state-of-the-art manufacturing facilities and customer collaboration centers for support whenever you need it

Related Products and Services:

- DOLCore[™] Intermediate
- ChetoSensar[™] Platform
- ADC Express[™] Services
- PBDCore™ Intermediate



The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

Comprehensive Solutions for Your ADC

We offer comprehensive supply chain reliability from discovery to commercialization of your ADC.

This includes coordinated and collaborative services for the development, manufacturing, and testing of bulk drug substance and drug product. We offer a full range of services to support your ADC projects:

- mAb, linker, payload conjugation development, and manufacturing services
- Analytical method development and validation
- · Technology transfer and manufacturing
- Stability studies for bulk drug substance and drug product
- Regulatory support

Industry Leadership for Single Nanogram containment

Our six new state-of-the-art high containment kilo labs were built with single-digit nanogram containment in mind and exhibit such features as:

- Extensive, integrated, multi-operation isolator technology to maintain full containment through the entire API synthesis, purification, and isolation
- Mechanical spaces to allow for all supporting devices to be kept outside of the labs

Manufacturing Capabilities

QTY	Equipment	Capacity	Temp Range
7	HPAPI Kilo Labs: Single ng OEL containment	g to kg scale	-75 to +190 °C
6	HPAPI Kilo Labs: Containment down to 30 ng/m³	g to kg scale	-75 to +190 °C
4	Potent Kilo Labs: Containment down to 1 µg/m³	g to kg scale	-75 to +190 °C
3	HPAPI Pilot Plants: Containment down to 30 ng/m³	120–800 L 3–25 kg batch	-20 to +180 °C
2	Potent Production Plants: Containment down to 1 µg/m³	2000 –4000 L 50–400 kg batch	-80 to +180 °C
	Column Chromatography	up to 40 kg silica	

ADCore payload intermediates

Advanced precursors to synthesize common payloads faster and with less risk

- Includes MAYCore[™], DOLCore[™], and PBDCore[™] products
- Enables rapid synthesis of maytansine, dolastatin-10, and PBD payloads
- Suitable for up to phase I clinical studies with process validation to support path to commercial approval
- Free samples available

ChetoSensar™ Platform

A technology that solves many challenges with antibody-drug conjugates

- Increased ADC solubility, particularly for higher DAR ADCs
- · Wider therapeutic index and higher drug efficacy
- · Improved bioconjugation efficiency

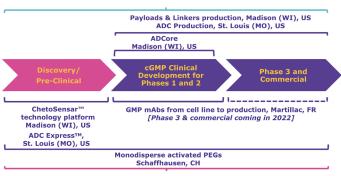
ADC Express™ Services

Pre-clinical conjugation services for the best candidate selection

- Mini-prep scale: 10-20 mg ADC construct ± column purification
- Medium-prep scale: up to 100 mg ADC ± column purification
- Certificate of testing with key quality attributes

ADC Contract Manufacturing Footprint

Analytical Testing and Product Characterization Rockville (MD), US



Successful use and scale-up of single use technology

For additional information, please visit sigmaaldrich.com/services/contract-manufacturing/high-potent-apis

To place an order or receive technical assistance, please visit sigmaaldrich.com/services/contact-safc

MilliporeSigma 400 Summit Drive Burlington, MA 01803

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