

SAFC®

Pharma & Biopharma Raw
Material Solutions

Millipore SIGMA



Dolastatin Core

An advanced precursor to synthesize
dolastatin payloads faster and with less risk

Accelerating Your Path to the Clinic

Dolastatin core is an advanced intermediate through which all known dolastatin 10 payloads can be made. We are excited to provide this innovative solution to meet your critical timeline needs.

Trust us for Your Payload Needs

- Significant expertise in linker-payload synthesis and drug conjugation
- Experienced in commercial supply and regulatory support
- Simplified supply chain with consolidated linker-payload and conjugation services

Product Features

- Enables rapid synthesis (3–4 synthetic steps) of all published dolastatin 10 payloads using this Dolastatin Core technology
- Suitable for up to phase I clinical studies with process validation to support your path to commercial approval
- Decreases time to clinic
- Royalty free use of the material

Dolastatin Core Features

- High purity material (HPLC Purity 97+%)
- 5 g samples available free of charge
- Full support for your regulatory filings

Related Products and Services:

- Advanced mertansine intermediate & DM1
- ADC Express™
- ChetoSensar™

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:

- 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

Payload and Linker Manufacturing Capabilities

We have more than 30 years of experience working with highly-active and complex molecules at our Madison, Wisconsin facility in the United States.

This site has a variety of manufacturing spaces and equipment to provide the necessary flexibility for multi-step synthesis of complex and highly potent APIs (HPAPIs) and linker-payloads. Our facilities are SafeBridge® certified for Category 4 materials.

ADC Express™

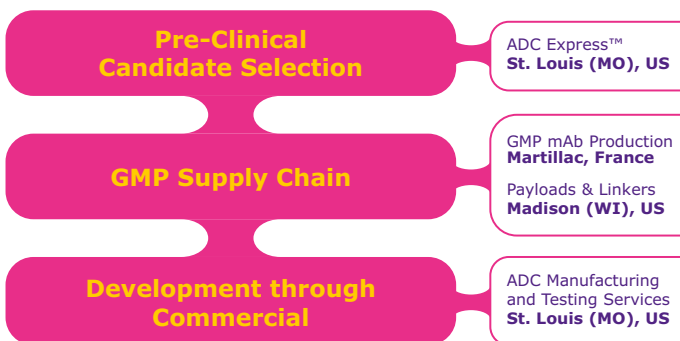
Pre-clinical Conjugation Services for the Best Candidate Selection

- 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 concentration
 - Payload density/DAR (drug antibody ratio)
 - Monomer/aggregate content
 - Endotoxin

Madison Facility Equipment List

QTY	Equipment	Capacity	Temp Range
7	Kilo Labs: Safebridge® Cat IV capable	g to kg scale	-75 to +190 °C
4	Kilo Labs: Safebridge® Cat III capable	g to kg scale	-75 to +190 °C
1	Safebridge® Cat IV drying/package suites	g to kg scale	-10 to +100 °C
1	Process Scale up Lab	g to kg scale	-75 to +190 °C
1	Hydrogenation Suite	2–100 L	-40 to +110 °C
11	Glass Lined Reactors	120–4,000 L	-30 to +180 °C
2	Glass Lined work up vessels	4,000–8,000 L	-30 to 80 °C
4	Hastelloy Reactors	200–2,000 L	-80 to +180 °C
6	Nutsche filter dryers	up to ~400 kg/batch	-30 to +70 °C
	Column Chromatography	up to 40 kg silica	
	Vacuum oven dryers	~4 kg	up to +100 °C
2	Lyophilizer, trays	~600 g/lot	-80 to +40 °C
	Varying filtration equipment		

ADC Contract Manufacturing Footprint



Learn more:

www.sigmaaldrich.com/US/en/services/contract-manufacturing/adc-bioconjugation

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

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

www.sigmaaldrich.com

