

## High Potent APIs

Cambrex is an innovative life sciences company with a refreshingly human approach. Driven by passion, our pharmaceutical products, expertise and technologies are accelerating small molecule therapeutics into the market to help businesses grow.

We offer our customers a truly end-to-end partnership for the research, development and manufacture of their small molecule APIs at every stage of the lifecycle.

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### High Potent APIs experience

Cambrex has been reliably developing and manufacturing a broad spectrum of HPAPIs and compounds for >15 years.

- Immunosuppressants
- Cytostatics/protein kinase inhibitors
- Ultra-potent cytotoxic drug substance
- Drug linkers
- PEG and cyclodextrin polymeric conjugations
- Drug product intermediates
- Antibody Drug Conjugates (ADC) payloads

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### High Potent APIs manufacturing capabilities

- Highly regimented safety protocols
- Controlled access to all areas
- Best-in-class barrier isolation
  - Process development
  - Scale-up of toxicology lot to commercial quantities in a cGMP environment
  - Development and manufacturing of HPAPIs and intermediates to 0.01 µg/m<sup>3</sup>
  - Lab scale cGMP manufacturing up to 20L
- cGMP kilo lab up to 150L
- cGMP pilot plant
- Commercial manufacturing up to 16,000L
- Multi-purpose solids handling suite
- cGMP micronization facility

### Occupational Exposure Limit (OEL) and Exposure Control Bands (ECB) Classification

- Mode of action and mechanism
- Toxicology data
- Chronic adverse effects
- Core chemical structure
- Dosage form and range
- Prior handling experience
- Comparison with known compounds



Jesper Kumlin  
Process Operator  
Production