

High potent APIs

High potent API experience

Cambrex can reliably develop and manufacture a broad spectrum of HPAPIs and compounds.

- Immunosuppressants
- Cytostatics/protein kinase inhibitors
- Ultra-potent cytotoxic drug substance
- Drug linkers
- PEG & cyclodextrin polymeric conjugations
- Drug product intermediates

High potent API 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/m³
 - 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) & Exposure Control Bands (ECB) classification

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



Brian Barlow
HIPO Operator,
HIPO

HIPO Capability Timeline

- 1998 HPAPI Compound Production
- 2006 HPAPI Kilo Lab and Micronization
- 2008 HPAPI Development Center
- 2019 Mid-scale Commercial HPAPI Expansion

Capability Highlights

- Capable of flexible setups using a variety of isolators, contained filter/dryer, flexible containment
- Contained drying and particle size reduction
- Bag-in/Bag-out technology
- Dedicated Operators with specific HIPO training

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.