

HIGHLY POTENT ACTIVE PHARMACEUTICAL INGREDIENTS



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CONTACT

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A GLOBAL PLAYER IN A GLOBAL MARKET

Heraeus specializes in the production of generic highly potent active pharmaceutical ingredients (HPAPIs) as well as the exclusive synthesis of cytotoxic compounds. Our support ranges from exclusive CDMO services in strict confidentiality throughout all phases of a product's life cycle to outstanding quality services.

All of our HPAPIs are fully developed and manufactured at our headquarters in Hanau, Germany. We have been US-FDA-approved for more than 30 years and have an excellent track record worldwide with all major Health Agencies.

With our passion for health care we achieved an outstanding global position in active pharmaceutical ingredients containing precious metals and highly potent anti-cancer treatments.

OUR GENERIC HPAPIS

We have developed a range of generic highly potent pharmaceutical ingredients for cancer therapy. The high purity of our HPAPIs guarantees you effective processes and consistently top quality for your products.

- Cisplatin
- Carboplatin
- Oxaliplatin
- Dacarbazine
- Thiotepa
- Bendamustine hydrochloride monohydrate
- Arsenic trioxide



CDMO SERVICES

We support our customers in the exclusive synthesis of cytotoxic compounds from the research stage to the market launch. With these comprehensive services, our customers are free to focus on their core business and transform their innovative ideas into commercial products:

- The high-containment systems ensure the highest technological standard (OEL down to 10 ng/m³)
- Extensive knowledge and experienced project teams
- Batches from gram to fully commercial scale
- Antibody Drug Conjugates (ADCs)
- Photochemistry reactions in batch and continuous flow production
- Comprehensive GMP documentation and outstanding global regulatory support – a full range of services under one roof
- Strictly protected customers' IP

OUR QUALITY SERVICES

Regulatory Affairs

We prepare and maintain all documentation for your initial and existing registrations worldwide. Our services are fully compliant with the strictest requirements for the quality of our HPAPIs:

- Management of registration procedures
- Professional ASMF / LoA / CEP handling
- eCTD submission
- Life Cycle Management
- Communication with health authorities
- Customer support

Quality Assurance

We constantly secure the outstanding quality of our active pharmaceutical ingredients and strictly follow international regulations. Our focus is to improve the quality, safety and environmental standards constantly:

- Release of HPAPIs
- Supervision of GMP compliance & quality
- Document management
- Internal and external auditing
- Training of staff and management
- Quality agreements

Quality Control

With more than 160 years of experience in quantitative precious metal analysis with highest accuracy and some 30 years in the quality control of HPAPIs, we are thoroughly established in performing a wide range of the latest analytical techniques:

- Release of raw materials
- Quality control of intermediates and HPAPIs
- Stability testing of HPAPIs and final dosage products
- In-process control
- Full characterization of reference standards
- Development and validation of analytical methods
- Identification of unknown impurities / degradation products



ABOUT HERAEUS

The Heraeus Group is a broadly diversified and globally leading family-owned technology company, headquartered in Hanau, Germany. The company's roots go back to a family pharmacy started in 1660. Today, the Heraeus Group includes businesses in the environmental, electronics, health and industrial applications sectors. Customers benefit from innovative technologies and solutions based on broad materials expertise and technological leadership.

Heraeus Precious Metals is globally leading in the precious metals industry. The company is part of the Heraeus Group and covers the value chain from trading to precious metals products to recycling. It has extensive expertise in all platinum group metals as well as gold and silver.

With about 3,000 employees at 15 sites worldwide, Heraeus Precious Metals offers a broad portfolio of products that are essential for many industries such as the automotive, chemicals, semiconductor, pharmaceutical, hydrogen and jewelry industry.

By 2025 Heraeus Precious Metals will be the first company in the industry that operates carbon neutral.

The outstanding experience in the ambitious handling and processing of precious metals has served as a basis for today's activities of our pharmaceutical ingredients: a market leader in selected highly potent active pharmaceutical ingredients (HPAPIs) for cancer treatment.