



Alpha



## Highly potent API capabilities

Eurofins Alpha offers its customers integrated API Development services for a wide range of API classes including Highly Potent APIs. These services are founded on the company's core strength of innovative Process Research & Development, Analytical Development, and cGMP Manufacturing with a reputation for delivering quality services and APIs of various potency to advance our clients programs. Within our facilities, we regularly produce clinical supplies as well as commercial APIs in the 10s of kilograms range.



## Facilities to support high potency APIs

Eurofins Alpha operations involving High Potency compounds are conducted with the highest level of work safety and regulatory compliance. Facility design, equipment, engineering controls and proper operation of facilities and equipment achieve the desired level of containment for HPAPIs. Fully contained facilities featuring single-pass, HEPA-filtered air and pressure-differential airlocks provide physical controls to prevent particulate migration. The various suites are isolated. Primary control is achieved by using fully contained equipment such as barrier isolators, engineered glassware, and closed system transfers.

- Alpha's R&D and Analytical Laboratories are equipped to handle Highly Potent APIs, up to SafeBridge Class IV
- Our cGMP Manufacturing Plant facilities can handle Highly Potent APIs of SafeBridge Class III up to 50kg scale
- APIs of SafeBridge Class IV can be supported in Alpha's dedicated kilo lab suite, for scales up to 5kg



Eurofins Alpha

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## Highly potent API capabilities

### Expertise

#### Research and Development

- Process Research & Development (PR&D) expertise to scale-up synthesis of APIs including synthetic route design / route scouting
- R&D synthesis of starting materials, intermediates, impurities and reference standards
- DoE during process optimization and to support later stage QbD studies
- Safety assessment of chemistry

#### cGMP Analytical

- Analytical method development and validation to monitor Starting Materials, In-Process and Final Release testing
- Forced Degradation (Stress) Studies
- Stability Studies to ICH requirements
- Cleaning validations
- Qualification of Reference and Impurity Standards

#### cGMP Production

- cGMP API manufacturing processes to meet customer and regulatory agencies' specifications and requirements
- QC, QA, Regulatory and CMC support
- Technology Transfer Specialists



### Project teams

Strong project management is an important component of our work. Every API Development & Commercialization project at Alpha is carried out by a talented group of Process Research Scientists, Analytical Scientists, Technology Transfer Specialists and cGMP Operators supported by a Project Manager. Project managers act as a clear point of contact for all discussions with the customer. This proven structure has been designed to ensure effective communication and project management and is reflected in the high levels of customer satisfaction for which we have developed a reputation.



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