eurofins | CDMO

HIGHLY POTENT API SERVICES

WHO WE ARE

Eurofins CDMO 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 for APIs of various potency to advance our clients' programs.

Within our USFDA & Health Canada approved facilities, we regularly produce clinical supplies as well as commercial APIs in the 10s of kilograms range.

OUR CAPABILITIES

Facilities to Support High Potency APIs

Eurofins CDMO 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.

Full containment 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 full containment equipment such as barrier isolators, engineered glassware, and closed system transfers.

NEW IN 2022

Addition of 2 walk-in fume hoods with up to 100L reactor capacity and~ 5kg single batch size!

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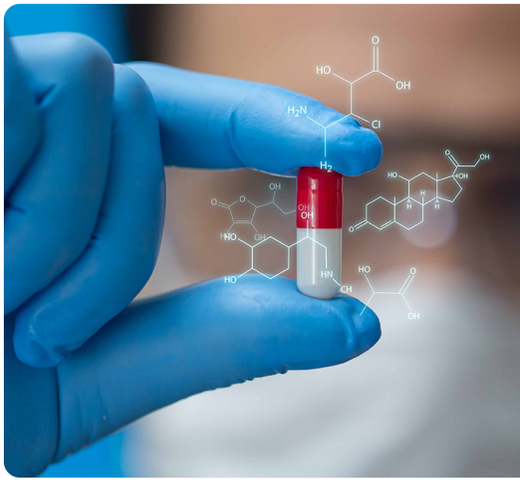
Eurofins CDMO in North America is equipped to handle APIs upto SafeBridge Class 4 (OEL's <30 ng/m³):

- Within our R&D and Analytical Laboratories
- In our dedicated cGMP Kilo Lab Suite and Walk-In Fume Hoods which scales up to ~ 5kg.

OUR EXPERTISE



Research & Development

- Process Research & Development (PR&D) expertise in APIs synthesis and scale up process development including synthetic route design/route scouting.
- R&D synthesis of starting materials, intermediates, impurities and reference standards.
- DOE, Spike, Fate and Purge studies to support process optimization, validation and commercialization stages.
- Process Safety Assessment.

cGMP Analytical

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

HIGHLY POTENT API SERVICES

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 Eurofins CDMO 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.

VISIT OUR WEBSITE

CONTACT US

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