

MINAKEM

Improving lives together



YOUR GLOBAL CDMO PARTNER

**EXCELLENCE IN CUSTOM
APIS AND HPAPIS**



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EXCELLENCE IN CUSTOM APIS AND HPAPIS

With 20 years of experience in process development, industrialization and GMP manufacturing of (H)APIs, Minakem ensures the security of supply with a well-established network of 4 full GMP sites in France, Belgium and Canada. We provide our customers with confidence in the availability of their product, to support successful launch and change the lives of patients globally.

A FIT FOR PURPOSE STRATEGY

Pre-clinical & Phase I

- **Quick and safe process** development to deliver API in a timely manner, in expected **quality**
- **Analytical methods development** for preliminary testing
- **Impurity profiling:** API characterization
- Early **identification** and **approval** of suppliers

Phase I to phase II

- **Robustness and scalability** improvement / **process optimizations**
- **Control strategy** definition
- **Stability indicating** methods development / **validation on specific criteria**
- **Impurity management** (PGI and NPGI)
- **Regulatory affairs** support

Phase II to phase III

- **QbD, CPP, impurity fate** and **purge**
- **Quality risk assessment, Nitrosamines testing**
- **Process and analytical validations**
- **Regulatory affairs** expertise
- **Elemental impurities**
- **Qualification** of suppliers / **Diversification program**

Commercial supply

- **Continuous Method Performance Verification**
- **Continuous improvement**
- **Stability studies**
- **Life cycle management** (dossier variations, process/analytical optimization...)

Key technologies

- Preparative HPLC (50. 110 and 300 mm)
- High containment (OEL 0.1µg/m³/8h)
- Pressure reactions (20 bar)
- Cryogenic chemistry (-80°C)
- Electrochemistry, photochemistry, flow chemistry
- Solid state and particle engineering
- Analytical expertise for all stages of development

R&D expertise

- Agnostic about the chemistry we do
- Broad expertise on modern and legacy reactions at various scales
- Innovation driven
- Green metrics to optimize processes
- Solid network with top-tier academic researchers

One partner from lab to commercial supply

LAB SCALE
20 g > 200 g

KILO - LAB
200 g > 2 kg

SMALL PILOT
2 kg > 20 kg

LARGE PILOT
20 kg > 200 kg

COMMERCIAL PRODUCTION
200 kg > 200 MT

Minakem consistently strengthens its dedication to sustainability

- Monitoring of GHG emissions since 2019
- Commitment to SBTi target "1.5°C" by 2030
- Water conservation program in accordance with CDP's guidelines
- Reducing our carbon footprint with renewable energy
- Ecovadis Gold rating



Your Trusted CDMO Partner for Success



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