

# High capacity, high-potency APIs

We move your high-potency active pharmaceutical ingredients (HPAPIs) from lab to large scale



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**Manufacturing highly potent APIs in large volumes requires extensive project experience with HPAPIs and a strong track record for audits and supply security. Only a few CMOs have the capabilities and experience to turn small-scale development lab quantities to large-scale commercial volumes with batch sizes of over 450 kg. If you are planning to produce large volumes of an HPAPI, come and see us early on and learn more about our experience and commercial manufacturing capabilities.**  
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Evonik has the world's largest manufacturing capabilities for HPAPIs, and more than 25 years' experience in this demanding business. We have set industry standards through a combination of our broad technology portfolio, superior process engineering, and unrivaled safety standards.

Many HPAPIs are synthesized through multiple process steps that require advanced technologies, such as asymmetric synthesis, transition metal catalysis or biocatalysis, PEGylation, continuous processing, and/or cryogenic reactions. Our interdisciplinary team draws on strong technical competencies to develop effective risk control systems based on a comprehensive assessment of exposure hazards and other safety risks for each step of the chemical synthesis.

## OUR FACILITIES AND EXPERTISE

Our Tippecanoe facility in Lafayette, Indiana, in the U.S. can run six different HPAPIs in parallel and has a total capacity of 170 m<sup>3</sup>. With containment capabilities down to an OEL of 0.1 µg/m<sup>3</sup>, the Tippecanoe site features numerous QC and process development facilities. The main unit of this multi-product facility is designed to prevent cross-contamination of products and ensure worker safety. Our industrial hygienists, maintenance teams, quality assurance experts, operations teams and

engineering and automation personnel have achieved an impeccable safety and containment record spanning 25 years of HPAPI manufacturing.

In our Hanau facility in Germany, we run process and analytical laboratories to develop and optimize HPAPIs requiring containment down to an OEL of 5 ng/m<sup>3</sup>. Manufacturing highly potent APIs is possible under GMP or non-GMP conditions.

*Overall, Evonik covers scales from lab up to 7,600 l reactor volumes.*

## THOROUGH QUALITY AND SAFETY PROCEDURES

We operate a comprehensive management system for the safe handling of HPAPIs. Our toxicologists and industrial hygiene specialists oversee our advanced cleaning methods and comprehensive waste treatment systems including on-site solids and liquids incineration. Tailored manufacturing equipment and robust analytical methods provide our customers with a global high potent network for drug substances.

### I) Custom drug substance services:

HPAPI development and cGMP lab scale manufacturing ( $> 5 \text{ ng/m}^3$ ),  
HPAPI production ( $> 0.1 \mu\text{g/m}^3$ )

### II) Custom drug product services:

Oral dosage forms (cGMP,  $> 1 \mu\text{g/m}^3$ ),  
Parenteral formulations ( $> 0.1 \mu\text{g/m}^3$ ),  
Oral dosage form development ( $> 0.1 \mu\text{g/m}^3$ )

## OUR SERVICES COVER A BROAD RANGE OF REACTION TYPES/TECHNOLOGIES

- Complex organic reactions
- Asymmetric synthesis
- Transition metal catalysis and biocatalysis
- Cryogenic reactions (e.g. organometallic)
- Milling of highly potent APIs (slurry, pin, jet mill)

## SCALABLE

The small, medium, or large-scale production of highly potent APIs at desired levels of quality consistency requires highly specialized process development and manufacturing capabilities, as well as a broad mix of associated advanced technologies.

### Process Development

Process and analytical laboratories for development and optimization of high-potency (to  $5 \text{ ng/m}^3$ ) intermediates and APIs

### Small Scale

Small-scale production for high-potency intermediates and APIs

### Medium Scale

Scale-up production for high-potency intermediates and APIs

### Large Scale

Large-scale high-potency intermediates and API production

#### PR&D Lab-scale

Hanau/Germany

$5 \text{ ng/m}^3$   
Glass lined

#### 20–50 gallon 75–190 liter

Tippecanoe/U.S.

$0.1 \mu\text{g/m}^3$   
hastelloy, glass lined

#### 500 gallon 1900 liter

Tippecanoe/U.S.

$0.1 \mu\text{g/m}^3$   
hastelloy, glass lined, steel

#### 2000 gallon 7600 liter

Tippecanoe/U.S.

$0.1 \mu\text{g/m}^3$   
hastelloy, glass lined

## Are you looking for support to develop and manufacture an HPAPI?

Let our highly skilled staff take you through the development, validation and commercialization of your drug substance.

**For more information contact:** Dr Ingo Klement, Director Global Business Development/Advanced Technologies:  
[ingo.klement@evonik.com](mailto:ingo.klement@evonik.com)

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**Evonik Operations GmbH**  
Health Care Business Line  
Exclusive Synthesis

[healthcare@evonik.com](mailto:healthcare@evonik.com)  
[evonik.com/healthcare](http://evonik.com/healthcare)