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Best-in-class API/HPAPI/ Small Molecules Custom Manufacturing



Six production locations – countless options.

USA: TIPPECANOE

- World's largest HPAPI capacity
- Four cGMP plants and pilot plant, 140 vessels, sizes 0.1–15.2 m³, cGMP kilo lab
- Development, scale-up and production facilities for HPAPI
- High-volume APIs, high-potency capabilities down to 0.1 µg/m³, low-temperature reactions, large-scale fermentation
- Twenty years of experience in manufacturing HPAPI

GERMANY: HANAU

- Three cGMP plants, including pilot plant, 42 vessels, sizes 0.16–8 m³
- API, cGMP hydrogenation, Cyanide handling, low-temperature chemistry, enzyme catalysis, organometallic chemistry

GERMANY: DOSENHEIM

- Two cGMP plants and one non-GMP multi-purpose plant, pilot plant, 36 vessels, sizes 0.05–12 m³
- APIs & Intermediates

FRANCE: HAM

- Three cGMP plants, including pilot plant, 34 vessels, 0.25–6 m³
- Amino acid purification
- Ion chromatography

SLOVAKIA: SLOVENSKA L'UPČA

- Fermentation of amino acids, API building blocks, Food ingredients
- Fermentation at pilot, 5 m³ and 50 m³ scale
- More than 1100 m³ total fermentation volume
- Various downstream capabilities

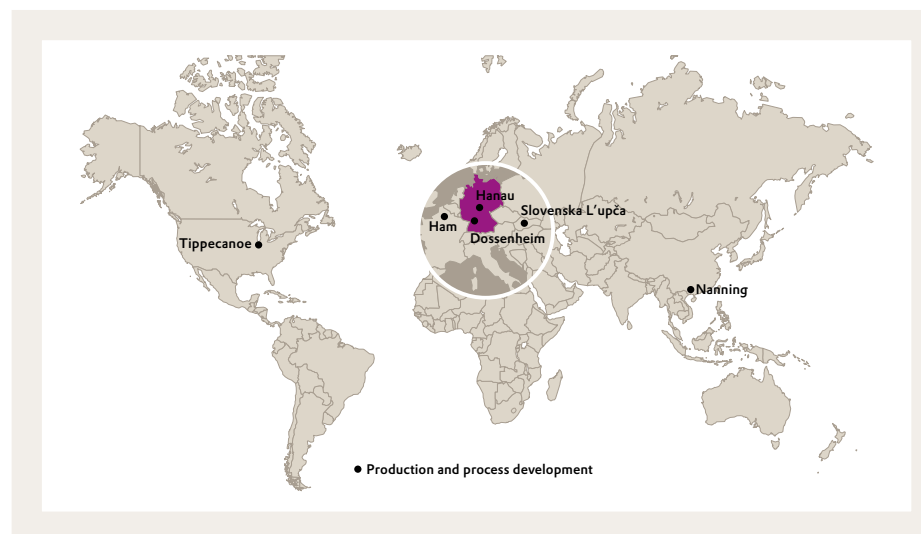
CHINA: NANNING

- Three cGMP plants and four amino acid plants, 47 vessels, 2.5–60 m³
- APIs, amino acids, fermentation, biocatalysis
- Crystallization and ion exchange technology



About Evonik

In 2016, our more than 35,000 Evonik employees produced sales of € 12.7 billion and an operating result (EBITDA) of € 2.165 billion. The pharma industry is part of the strategic core business of Evonik, and it has been for several decades. At Evonik, our track record builds on 40 years of experience in the production of pharmaceutical products. Our Health Care Business Line is firmly embedded within the Evonik Group, enabling us to promise our customers stability and staying power – essential for building long-term partnerships. It is one of the top three global players in the pharmaceutical custom manufacturing arena and has the world's largest HPAPI capacity.



Highlights of our core competences

- API/Intermediates production in Germany, USA, France, China and Slovakia
- GMP/nonGMP reactors up to 15,200 l
- Cryogenic capacity 200 m³ (Reactions down to – 80 °C)
- HPAPI capacity 170 m³ (OEL down to 0.1 µg/m³)
- HPAPI cGMP lab: OEL down to 5 ng/m³
- Fermentation reactor volume: 4000 m³
- Large-scale ion chromatography
- Continuous processes (2/3 of Evonik products are produced continuously)
- Highly pure mPEGs

A unique portfolio

API/HPAPI CAPABILITIES & SERVICES

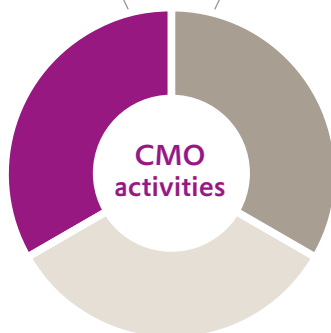
- World's largest HPAPI process developer and producer
- API at any scale from few kg to hundreds of mtons/year (only exceptions: β -Lactams, hormones) from plants in the US, Germany, France and China
- Full service: process development, particle design, optimization, production

TECHNOLOGY & CHEMISTRY PORTFOLIO

- World's largest cryogenic capacity and organometallic expertise
- Catalyst screening and manufacturing
- Evonik continuous reaction platform (2/3 of Evonik products produced continuously)
- Very strong basis in process engineering and rapidly building/tailoring of new or existing plants

CHIRAL CHEMISTRY & BIOTECHNOLOGY

- Enzyme experts – 20 different enzyme types already used in production up to very large volumes
- Full service offering for enzymes, fermentation, strain development
- Very broad technology platform for chiral products including chemo- and biocatalysis



API/HPAPI CAPABILITIES & SERVICES

HIGHLY POTENT API (HPAPI)

- World's largest HPAPI capacity
- Leading HPAPI producer for more than 20 years
- Main site Tippecanoe Laboratories, Lafayette, IN, USA
- From lab scale up to 8,000l reactor volume
- Total capacity: 170 m³, OEL down to 0.1 $\mu\text{g}/\text{m}^3$

API FOR CLINICAL AND COMMERCIAL SUPPLY

- Global Top 3 API producer
- FDA-inspected plants in Germany, US, China, France
- Total cGMP reactor volume > 1000 m³
- Large-volume cGMP reactors up to 15,200l
- Development and manufacturing of very complex multi-step API

CONTROLLED API/HPAPI

- European and US-based production
- US (DEA) and European controlled API

API CONJUGATION

- Conjugation of API (e. g. PEGylation)
- Different conjugation technologies for API
- Expertise in linker chemistry
- Highly pure mPEGs and PEGylation

PARTICLE DESIGN

- Dedicated lab and experts
- Development of crystallization, polymorph control, solid/liquid separation, drying, particle size control
- Broad range of milling technologies and equipment
- Spraydrying expertise including nonGMP commercial scale equipment

TECHNOLOGY & CHEMISTRY PORTFOLIO

ORGANOMETALLIC AND CRYOGENIC CHEMISTRY

- World's largest cryogenic capacity: > 200 m³ cryogenic reactor volume
- Reactions down to -80 °C
- Up to 8,000 l cryo reactor volume
- Aromatic/heterocyclic boronic acids

HOMOGENEOUS/HETEROGENEOUS CATALYSIS, HYDROGENATIONS, CARBONYLATIONS, X-COUPPLINGS

- Suzuki, Heck, Sonogashira, Kumada, CN-Coupling, ...
- Backward integration
- Up to 20 bar in batch reactions
- Up to 200 bar in continuous processes
- HTS (library with >1000 catalysts)

HETEROCYCLIC CHEMISTRY

- More than 50 years experience
- Nitrogen, oxygen and sulfur heterocycles

HIGHLY TOXIC REAGENTS, SENSITIZERS, ...

- Cyanide/HCN chemistry
- Epichlorohydrin
- Phosgenation (Triphosgene)
- Handling of highly sensitizing materials
- Thiophosgenation

PHOSPHOROUS CHEMISTRY

- Wittig, Horner-Emmons reagents
- Phosphonium salts

CONTINUOUS PROCESSES

- More than 50 years of experience
- Tube reactors, CSTR, loop reactors
- 2/3 of all Evonik products are produced in a continuous manner
- Expert lab for continuous processes

SEPARATION TECHNOLOGIES

- Up to 60 theoretical plates
- Short path and wiped film distillations
- Rectifications
- Large-scale ion chromatography

PROCESS ENGINEERING

- Extensive in-house Process Technology & Engineering capabilities
- From feasibility study to execution
- Investment projects of up to 500 Mio€ realized

HIGHLY PURE mPEGs

- More than 30 years experience in PEG manufacture
- Pharma grade mPEGs with low polydispersity and diol content
- Strong expertise regarding activated mPEG under cGMP

CHIRAL CHEMISTRY & BIOTECHNOLOGY

CHIRAL CHEMISTRY, CARBOHYDRATES, NUCLEOSIDE CHEMISTRY

- From chiral pool to advanced chemo- and biocatalysis
- Carbohydrates: chemistry and purification
- Broad technology range for nucleoside API

AMINO ACIDS AND DERIVATIVES

- Natural and nonnatural amino acids
- Extensive biotech and chemistry portfolio
- Di- and tripeptides

BIOCATALYSIS AND ENZYME CHEMISTRY

- Isolated enzymes and whole cell processes,
- In-house enzyme library
- Experience > 20 different enzyme types
- From directed evolution to large-scale production
- Acylases, alcohol dehydrogenases (ADH), aldolases, amidases, amino acid dehydrogenases, transaminases, lipases, oxynitrilases, ...

FERMENTATION

- Total fermentation volume almost 4,000 m³
- From strain development to commercial manufacturing
- Leading global player
- Application of different organisms (especially bacteria and yeast)