We are your long-term partner of choice

API Polpharma is a significant European producer of Active Pharmaceutical Ingredients delivering products to pharmaceutical companies worldwide. We are present on 6 continents, in 60+ countries, and our market share is constantly growing. Our well-balanced and expanding portfolio, along with our scientific know-how and experience, allow us to offer attractive solutions for drug developers.

We provide a one-stop shop solution of vertically integrated services from API development to FDF formulation and manufacturing, scale-up capabilities based on in-house or external custom developed technologies, to regulatory support.

Regular FDA audits enabled us to register and sell a number of APIs in the US market and confirm our reliability and credibility towards our business partners around the world. At Polpharma quality comes first.

Core competences

Our products are manufactured in accordance with the most stringent requirements of our customers and health authorities. DMF documentation for all our products is prepared in accordance with the latest requirements of EDQM (CEP), ICH (EuDMF, CTD), and FDA (US DMF).
Material and product testing is performed in line with the European and United States Pharmacopeias. However, our products can be additionally tested in compliance with the customer's specifications.

Building future

We are responsive to the ever-changing dynamics of global markets. Seeing how rapidly the demand for active pharmaceutical ingredients grows, we decided to significantly increase productivity within this area by investing into a complex modernization of API production lines.

WE INVEST WITH YOUR FUTURE IN MIND

A completely rebuilt and modernized production facility for the production of API was put into operation in February 2017 extending our production capacity.We invest in innovative technologies which enhance production efficiency, the comfort of medication delivery and safety of our processes for humans and the environment

Our newly modernized facility is compliant with the highest manufacturing standards. Equipment delivered by globally recognized suppliers ensures safety of API production in conformity with Polpharma quality standards as well as increasing cGMP requirements. Our production area has been designed to enable parallel manufacturing of API on two additional production lines

Our offer

Professional and experienced team

Team of key account managers guarantee customized service packages for each client. We are here to advise in project evaluation, educate our clients about our technology and recommend appropriate solutions. We provide assistance in every step of the purchasing process.

Control over your product

The scope of our services includes preparation of comprehensive regulatory documentation in an eCTD format.

The process is performed by the R&D, RA, QA and other Operational departments of Polpharma. All of this with the sole purpose of maintaining full control over your product.

Full support

Polpharma API offers full support from process optimization, analytical method development & validation, to process scale-up to pilot plant (kg scale) and fully commercial, multiple tons synthesis in EU cGMP, FDA (US), Anvisa (Brazil), PMDA (Japan) & KFDA (Korea) approved facility.

We offer solutions tailored to your needs:

- Full support from molecule development to drug delivery
- Development and production of generic APIs
- Custom synthesis and toll manufacturing
- Intellectual Property expertise and guidance
- Regulatory compliance
- Process upscaling
- Development of new salts and polymorphic forms of APIs
- Adjusted particle size distribution (PSD)
- Non-infringing process development
- Multipurpose production lines
- High GMP standards
- High quality products
- Excellent service
- Wide reaction classes in FDA approved facilities