



Hedinger, founded in 1843, with an experience of 180 years offers customized solutions to their customers.

Since many years Hedinger is undertaking huge investments including time and expertise into advancing the Hedinger-GMP/ GDP-System to become one of the world's leading quality specialists in supplying starting materials to the global pharmaceutical industry.

Hedinger always strives to provide the best products, handled according to the highest standards of the pharmaceutical industry inkl. a customized service package to their customers all over the world. With the Headquarter in Stuttgart, Germany and a production site in Teutschenthal, Hedinger has a robust set-up to fulfil the highest requirements in terms of quality, safety and cost efficiency.

Complying with the differing requirements, Hedinger carries out all manufacturing processes according to the IPEC PQG GMP Guidelines, IPEC GDP Guidelines and EU-GMP Part II. There are 4 Clean-rooms class D (100.000) at each site – 8 Clean-rooms in total to carry out all GMP-operations.

For analytical testing 2 state-of-the-art GMP-Laboratories are fully equipped and highly educated scientists, including 5 Qualified Persons according to EU-GMP, release all products.

All products are handled with product dedicated equipment only, most products are directly collected by Hedinger from the manufacturing site with own dedicated tank trucks. At Hedinger we keep full traceability along the entire supply chain until the product is in the warehouse of the end-customer. We challenge our Quality- and Environmental-System regularly by audits from global customers and the local competent authorities.

For many products Hedinger has agreed defined manufacturing conditions with their partners up to GMP-conditions. The partners, specialists for each product, are amongst the leaders in their own field. For decades Hedinger has a strong "One Product – One Partner" strategy underlining the long-term of these close partnerships. Several products have been co-developed to meet the needs of the pharmaceutical customers. These very close relationships between Hedinger and the Raw-Material producers allow Hedinger to perform audits at their production sites. The audit reports can then be shared with the end-customers.

Hedinger holds the following certifications

- ISO 9001
- ISO 14001
- ISO 45001
- EU-GMP Part 1 and 2
- EXCiPACT™ GMP & GDP
- AEO-F & Known Consignor

Dow



- Propylene Glycol Ph. Eur./USP/JP¹
- Propylene Glycol Ph. Eur./USP/JP parenteral grade¹
- Macrogols Ph. Eur./USP (NF) CARBOWAX™ SENTRY™ Polyethylene Glycols

Olin (Blue Cube)



- Glycerol Ph. Eur./USP/JP 99.7% (synth.)
- Glycerol Ph. Eur./USP/JP 99.7% (synth.) LA parenteral grade¹
- Glycerol 85% Ph. Eur.³
- Glycerol 85% Ph. Eur./JP LA/API/parenteral grade^{1,3}

Oleon

- Glycerol Ph. Eur./USP (vegetable)
- Glycerol Ph. Eur./USP/JP parenteral grade (vegetable)
- Glycerol 85 % Ph. Eur. (vegetable)³

INEOS Phenol



- Acetone Ph. Eur./USP (NF)/JPE INEOS Acetone SQ

Shell Chemicals



- Isopropyl Alcohol GMP Ph. Eur./USP/JP (pharmaceutical starting material/biocidal active substance)
- Isopropyl Alcohol 70% API grade/biocidal product³
- Isopropyl Alcohol 70% (V/V) API grade/USP Isopropyl Rubbing Alcohol USP³
- Petroleum Spirit (boiling range 40°C to 60°C) DAB

Arkema



- Hydrogen Peroxide Solution (30%) Ph. Eur. API grade

Lanxess



- Metacresol Ph. Eur./USP parenteral grade¹
- Butylhydroxytoluene Ph. Eur./USP/JPE GMP grade²

INEOS Acetyls



- Acetic Acid, Glacial (99.9%) Ph. Eur./USP/JP
- Acetic Acid, Glacial (99.9%) Ph. Eur./USP/JP parenteral grade
- Acetic Acid 80% API grade³
- Acetic Acid, customised aqueous solutions

Hedinger



- Purified Water Ph. Eur. / Highly Purified Water Ph. Eur./USP
- Sodium Hypochlorite Solution 1% and 3%³
- Customized Aqueous Solutions
- Customized clean-room repackaging
 - in our two GMP-inspected manufacturing plants
- Customized testing & release
 - in our two EU-GMP Part 1-certified laboratories

¹ Fully registered in CDE database for China

² Ongoing registration for China

³ Produced with Purified Water Ph. Eur. / Highly Purified Water Ph. Eur./USP

