



IOI OLEOCHEMICAL

PHARMA

ENGINEERED LIPID EXCELLENCE

QUALITY & REGULATORY



EXCIPIENTS & ACTIVE PHARMACEUTICAL INGREDIENTS - MADE IN GERMANY

Founded in 1905, IOI Oleo's manufacturing site in Witten has been engaged since the beginning of the 1950s in the manufacturing of high-quality oleochemical specialties. Following the expansion of chemical expertise and demand for new materials, our brands **MIGLYOL®**, **IMWITOR®**, **SOFTISAN®**, **WITEPSOL®**, **SOFTIGEN®** and **DYNASAN®** have been introduced to exceed quality requirements for excipients in health-care, cosmetics, nutrition and technical applications around the globe.

OUR RECIPE FOR SUCCESS: SYSTEMATICALLY THE BEST QUALITY

From the purchase of raw materials, production and sales right on to employee development and sustainability management – adherence to the highest quality standards has top priority in all corporate areas. We make every effort with this comprehensive, integrated management to supply our customers consistently with both: products of the highest standards and services that you can rely on.

Therefore, we use only high-quality raw materials from selected and approved suppliers, which we then process into our lipid excipients and active pharmaceutical ingredients under strict rules of product safety and hygiene. Naturally, we supervise our skilled and experienced production employees throughout the manufacturing process, before the final release analysis is performed by our Quality Control department followed by final approval in the Quality Assurance department.

OUR FOCUS ON SUSTAINABILITY

IOI is committed to fully integrating sustainability and the careful use of resources into our entire business activities. In addition to the RSPO SCCS certification, we are a member in a variety of committees and platforms (e.g. Ecovadis and Associate member of the PSCI) in order to provide our customers with the greatest possible transparency. Furthermore, our environmental management system is certified according to ISO 14001 and conforming to EMAS.

OUR HIGH STANDARDS: DOCUMENTED AND CERTIFIED

Today, our Witten site operates according to cGMP quality management standards and is regularly inspected by the US FDA and our local German health authority.

We practice compliance with various regulations and standards. This is important both for patient safety and for the extensive collaborations we already have in the pharmaceutical world.

- CEP holder for **MIGLYOL® 812 N** (API-grade)
- Type II US DMF for **MIGLYOL® 812 N**
- Type IV US DMF for **MIGLYOL® 810 N/812 N** and **IMWITOR® 742**
- China registrations for **MIGLYOL® 812 N** (API-grade) and **IMWITOR® 742**
- EU GMP certificates



- ✓ ISO 9001 & ISO 45001
- ✓ EMAS
- ✓ RSPO SCCS
- ✓ EU GMP certified
- ✓ US FDA cGMP inspected
- ✓ HACCP
- ✓ Halal/Kosher
- ✓ Cosmos/Ecocert



OUR EXPERIENCE IN GMP-COMPLIANT PRODUCTION

SOPs, validations and documentation, regular audits by health authorities, certification bodies and customers are an integral part of contemporary, state-of-the-art quality management.

Continuous improvement is an integral part of our company philosophy: converting and applying quality principles, developing and improving processes, measuring and evaluating the results in an industrial scale manufacturing setting. In anticipation of future developments and requirements, IOI Oleo constantly challenges the status quo to deliver products with the appropriate quality for every application.



This ongoing process has resulted in several major investments setting new standards in the legally sensitive pharmaceutical industry:

- + Ultrapure process water is created on site by means of reverse osmosis, ion exchange and UV treatment.
- + Since 2016, the pastillation of WITEPSOL® hard fats is performed in a Class D clean room environment, and is completed by a fully automatic packaging process without manual operations. The pastillation and packaging of several thousand tons of de novo synthesized lipids per year takes place at the manufacturing site in Witten.
- + In 2019, IOI Oleo completed the establishing of a new building for filling API grade ester oils. The new facility features a Class D cleanroom with automated filling procedures and packaging handling. Without question, design and floor planning were completely in accordance with applicable regulations and state-of-the-art hygiene standards.

IOI strives for quality and excellence in all our activities through continuous improvement - for our customers, our employees and our environment.

**Leading global expert and innovator
of functionalised ester-based lipids
with added value for pharma solutions.**

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