



IOI OLEOCHEMICAL

PHARMA

Commitment to Excellence in

Quality & Regulatory





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SUSTAINABILITY AT IOI OLEO GMBH – A CORE VALUE IN ACTION

At IOI Oleo GmbH, sustainability is not just a guiding principle — it is a fundamental part of our corporate identity and daily operations. We are committed to responsible resource management and environmental stewardship across all areas of our business.

Our dedication is reflected in our RSPO SCCS certification and our active participation in leading sustainability platforms such as EcoVadis and the Forum for Sustainable Palm Oil (FONAP). These affiliations enable us to provide our customers with maximum transparency throughout the supply chain. We are proud to be EMAS-certified, demonstrating our commitment to continuous environmental improvement through a robust and transparent environmental management system.

In recognition of our efforts, IOI Oleo GmbH is repeatedly top rated by EcoVadis, highlighting our strong performance in sustainability. Sustainability is one of our six core corporate values and is firmly embedded in our everyday practices. As part of our long-term vision, we have committed to achieving Net Zero by 2040 — a significant milestone on our journey toward a more sustainable future ...



OUR HIGH STANDARDS: DOCUMENTED AND CERTIFIED

At our Witten site, we are committed to upholding the highest quality standards by adhering to stringent GMP quality management guidelines. Regular inspections by the US FDA and the local German health authority ensure compliance with all relevant regulations.

We hold the following certifications and standards:

- ✓ EU GMP certificates
- ✓ ISO 9001 & ISO 45001
- ✓ EMAS environmental management
- ✓ RSPO SCCS certification
- ✓ US FDA cGMP inspections
- ✓ HACCP
- ✓ Halal/Kosher certifications
- ✓ Cosmos/Ecocert

These comprehensive certifications and our strict compliance with regulations ensure not only patient safety but also successful collaborations with our partners in the pharmaceutical industry.



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



OUR RECIPE FOR SUCCESS: QUALITY AT THE HIGHEST LEVEL

Quality is our top priority – from the selection of raw materials and production to employee development and sustainable management. Our goal is to consistently provide our customers with products and services that meet the highest standards.

We exclusively use premium raw materials from carefully selected and approved suppliers. These are processed under strict safety and hygiene standards into our lipid excipients and active pharmaceutical ingredients.

Our skilled production employees are supervised throughout the manufacturing process, followed by final analysis by our Quality Control department and approval by our Quality Assurance team. With a comprehensive, integrated management approach, we ensure that our products and services consistently meet the highest standards – reliable and without fail.

OUR EXPERIENCE IN GMP-COMPLIANT PRODUCTION

Our commitment to compliance is reflected in the rigorous implementation of Standard Operating Procedures (SOPs), comprehensive validations, meticulous documentation, and regular audits conducted by health authorities, certification bodies, and customers. These elements form the foundation of our modern, state-of-the-art quality infrastructure.

Continuous improvement is a core element of our company philosophy. We focus on implementing and refining quality principles, optimizing processes, and evaluating results on an industrial scale. Anticipating future developments and requirements, IOI Oleo consistently challenges the status quo to deliver products with the appropriate quality for every application.

This commitment to excellence has led to significant investments that set new benchmarks in the highly regulated pharmaceutical industry:

Purified Process Water: Produced on-site using reverse osmosis, ion exchange, and ultra-filtration combined with UV treatment.

WITEPSOL® Hard Fats Pastillation:

Since 2016, pastillation has been performed in a hygienic controlled environment, complemented by a fully automated packaging process without manual intervention.

API-Grade Ester Filling Facility:

In 2019, a new building was established featuring a hygienic controlled environment with automated filling and packaging procedures. The design and layout were fully aligned with applicable regulations and state-of-the-art hygiene standards.

IOI Oleo strives for quality and excellence in all activities through continuous improvement – for our customers, our employees, and the environment

**We're here to help –
Reach out for personalized
Quality & Regulatory support**

REGULATORY CERTIFICATIONS: A STRATEGIC ADVANTAGE FOR OUR CUSTOMERS

Offering active ingredients and excipients with global certifications isn't just about compliance — it's about delivering value, trust, and speed to our customers.

Our certification portfolio includes:

- **CEP (Certificate of Suitability)** – trusted across Europe for quality and regulatory alignment.
- **US DMF Type II & IV** – supports FDA filings and builds confidence in the U.S. market.
- **China CDE registration** – enables smoother access to one of the world's largest pharma markets.

What this means for our customers:

- **Faster product approvals** and reduced regulatory complexity
- **Reliable, validated quality** that meets international standards
- **Global market access** with fewer barriers
- **Stronger partnerships** built on transparency and trust

With these certifications we help our customers bring products to market faster, reduce risk, and stay competitive — worldwide.

	EU CEP	US DMF TYPE II	US DMF TYPE IV	CHINA CDE REGISTRATION
MIGLYOL® 812 N	X	X	X	X
MIGLYOL® 810 N			X	X
IMWITOR® 742	X		X	X
WITEPSOL®			X	X

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