



IOI OLEOCHEMICAL

PHARMA

Commitment to Excellence in

Quality & Regulatory





IOI OLEOCHEMICAL

OUR COMMITMENT IN PRACTICE

IOI Corporation Berhad (IOI) is a long-standing member of the Roundtable on Sustainable Palm Oil (RSPO) and operates certified palm oil production facilities and plantations. The company has established policies, management systems and programmes related to environmental, social and supply chain topics across its operations. These principles are reflected in IOI's vision, core values, policy statements and operational practices. IOI regularly reviews and further develops its processes and management systems as part of its ongoing business activities.

Our Projects and Initiatives

Across our operations, we carry out projects and programmes addressing topics such as greenhouse gas emissions, resource efficiency, supply chain management and biodiversity-related measures. Our approach is supported by policies, standards and codes of conduct that apply across the organisation and to relevant business partners. In addition, we participate in community engagement activities and support selected non-profit organisations.

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 over the production up to employee development. 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 – without ceasing.

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

IOI Oleo GmbH
Hamburg, Germany
+49 40 28 00 31-0
pharma@ioioleo.de
www.ioioleo.de

Important notice

All trademarks displayed in this brochure are the property of IOI Oleochemical's group of companies except as otherwise marked. Users of this brochure are not permitted to use these trademarks without the prior written consent of their proprietor. All rights are reserved. Reference to trademarks used by other companies is neither a recommendation, nor should it give the impression that products of other companies cannot be used.

Disclaimer

IOI Oleo GmbH makes no representations or warranties, neither express nor implied, on the suitability for specific medical device or pharmaceutical applications of the products to which the information refers. In particular, the customer is fully responsible to determine end-use suitability and is not exempted from the obligation to conduct careful inspection and testing of incoming goods.