

The Confidence of Partnering with the Global Leader

Lipid APIs and Intermediates



Creating Health Solutions



Excellence from us.
Confidence for you.™

The Confidence of Partnering with the Global Leader for Lipid APIs & Intermediates

KD Pharma is the global leader in **lipid-based Active Pharmaceutical Ingredients (APIs) and Intermediates**. With the industry's widest technology portfolio, rigorous quality standards, and entrepreneurial flexibility we give our partners the confidence to innovate and grow.

Why Partnering with KD Pharma Gives You Confidence

With a focus on lipids innovation and manufacturing for nearly **40 years**, KD Pharma combines quality excellence, regulatory expertise, and unmatched supply capabilities. Our partners rely on us for flexibility, reliability, and the confidence that comes from working with a trusted leader.

We provide the complete foundation for success in lipid-based pharmaceuticals.

Lipid Portfolio

Omega-3 APIs

- Largest producer of Omega-3 APIs worldwide
- Ultra-high purity: EPA up to 99%, DHA up to 95%, tailored ratios
- Multiple formats: ethyl esters, triglycerides, free fatty acids, phospholipids

Lipid Derivatives & Mediators

- R&D flexibility for customer-specific lipid structures
- Expertise in complex, multi-step purification technologies
- Comprehensive analytical support from our GMP-regulated laboratory

Lipid CDMO Services

- Custom development of lipid APIs & intermediates
- Customer-specific R&D and development support
- Flexible approaches to complex lipid development
- Regulatory and Quality support for DMF/CEP submissions and other regulatory dossiers



Leading the Way in Quality Excellence

KD Pharma is a multiple award winner in the worldwide **AOCS Laboratory Proficiency Test** for the analysis of Omega-3 oils (GOED Nutraceutical Oils series) and received **GOEDs Award** for the Highly Accurate Quantification of the Fatty Acids EPA & DHA (2024, 2025 and 2026).

- Robust Quality System: Global standards for document control, validation, and risk management
- Trusted Suppliers: Only qualified raw materials meeting strict standards
- Multiple certifications across various global sites, including ISO, GMP, FDA, and Halal
- State-of-the-art laboratory technology and methods in accordance with various pharmacopoeias

Quality is at the heart of everything we do.

Unmatched Market Position

KD Pharma's advanced technologies and strategic sourcing make us the preferred partner for lipid APIs and Intermediates.

- With the **industry's broadest lipid technology portfolio**, we empower partners with the flexibility to achieve optimal results
- Pioneering use of **Supercritical Fluid Chromatography (SFC)** for fatty acid separation and several patented lipid purification methods and formulations
- Direct access to raw materials with priority purchasing from quota holders
- Largest buying power in the global fish oil market securing supply to your business

A market advantage that keeps our partners ahead of the curve.

Regulatory Support for Global Filings

KD Pharma's omega-3-based API is approved for use in drug products in approximately 50 countries worldwide. Our regulatory expertise ensures that customers can move forward with confidence – from development to approval.

- DMF and ASMF preparation and filing.
- CEP and ANDA applications
- Strong focus on Icosapent Ethyl and Omega-3 Acid Ethyl Esters compliance and approvals.
- Any range of intermediates for Omega-3 APIs adapted to global requirements

KD Pharma produces according to the requirements of official compendia such as:

- US, EU and Japanese Pharmacopoeia
- World Health Organization (WHO)
- Global Organization for EPA & DHA Omega-3 like GOED and AOAC

You can move forward with confidence.

Reliable Manufacturing. Agile Delivery.

We give our partners reliable supply and a competitive market edge.

- Batch size flexibility to match customer requirements
- Short production lead times to accelerate time-to-market
- Consignment stock options for supply security
- Fast response to orders through a global supply network
- Flexible order management to support customer needs

From production to delivery, we turn supply into your strategic advantage.

Your Partner for Sustainable Omega-3s

We unite rigorous quality with responsible sourcing and manufacturing to deliver high-integrity lipid solutions.

- Certified environmental & energy management (ISO 14001, ISO 50001)
- Accredited according to ISO/IEC 17025 for the scope of accredited testing methods.
- 100 % traceable, responsibly sourced marine oils (MSC, FOS, IFOS)
- **Solvent-free processes** and maximum resource efficiency
- Global cGMP systems powered by renewable energy and waste reduction

A committed partner to a sustainable future.



Omega-3 API and drug substances

KD Pharma's Approved Pharmaceutical Ingredients (APIs, mg/g)	EPA	DHA	EPA + DHA	OMEGA-3 FATTY ACIDS
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Omega-3 Acid Ethyl Esters

460380EE (EP)	430-495	347-403	800-882	NLT 90%
465375EE (USP)	430-495	347-403	800-880	NLT 90%
46037EE (JP)	430-495	347-403	800-880	NLT 90%

Icosapent Ethyl

EPA965EE (EP & USP)	965-980	not defined	not defined	not defined
EPA96% (JP)	96.5%-100.0%	not defined	not defined	not defined

EP - European Pharmacopeia, USP - US Pharmacopeia, JP - Japanese Pharmacopeia

The table above outline our existing DMF products. Additionally, KD Pharma is capable of developing a variety of customized compositions according to your needs.

KD Pharma sets the standard in lipid manufacturing — trusted worldwide for innovation, quality, and reliability.

Let's advance healthcare together.
Contact us at: info@kdpharmagroup.com

Learn more about KD Pharma at:
www.kdpharma.kdpharmagroup.com



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