# The Confidence of a Global Leader for Lipid APIs & Intermediates



Creating Health Solutions





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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

#### **Cannabinoids**

 Industrial solutions for plant-sourced API raging from CBD 99,9%, THC 99,9% and magistral preparations

#### **Lipid Derivatives**

- R&D flexibility for customer-specific lipid structures
- Comprehensive analytical support for quality control

#### **UltraPure™ Excipients**

• Developing UltraPure™ Glycerol: Proprietary purification removes impurities, including oxidative byproducts for unmatched purity



#### 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 and 2025).

- 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)
- 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
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

