

PRODUCTS DATASHEET

Active Pharmaceutical Ingredients (API)

Product

Omega-3-acid Ethyl Ester (90)

DMF No. 22285 U.S. FDA cGMP approved

Specification

Test	Unit	Acceptance Criteria
Appearance		Colorless to pale yellow, clear
Cold test 3 h/ 0°C (Stearin)		Clear
Assay	mg/g	EPA: 430 Min
	mg/g	DHA: 347 Min
	mg/g	EPA+DHA: 800 Min
	%	total omega-3-acid: 90% Min
Absorbance 233 nm	AU	0.5 Max
Cholesterol	mg/g	3.0 Max
Oligomers	%	1.0 Max
Acid value	mgKOH/g	1.0 Max
Peroxide Value	meq/kg	5.0 Max
Anisidine value		15 Max
TOTOX		25 Max
Asenic (As)	mg/kg	0.1 Max
Lead (Pb)	mg/kg	0.1 Max
Mercury (Hg)	mg/kg	0.1 Max
Cadmium (Cd)	mg/kg	0.1 Max
DDT (sum: p,p'-DDE + o,p'-DDT + p,p'-DDT + o, p'-DDD + p,p'-DDD)	mg/kg	0.05 Max
HCB	mg/kg	0.05 Max
Lindane	mg/kg	0.05 Max
PCBs	mg/kg	0.09 Max
Dioxins like PCBs	pg /g	3 Max
PCDDs + PCDFs (Dioxins + Furans)	pg /g	1 Max
PCDDs + PCDFs + dioxin-like PCBs	pg /g	4 Max
Limit of total unidentified fatty acids	% (peak)	single 0.5% Max, total: 2% Max

Storage: Stored in unopened original closed container, protected from light and heat.

Packaging: Steel drum with protection under nitrogen atmosphere, 190 kg net

Shelf Life: Maximum 24 months.

Antioxidants: 2.8~4.5 mg/g of GMO free natural α -tocopherol can be added at customers requests.