INFY LIFE SCIENCE

ADDRESS: SHED NO 23, Block No 75, B & 234, SAI PRASAD INDUSTRIAL ESTATE, Santej - Vadsar Rd, opp. Nathika Casting, nr. Kapasi Industrial Park Road, Gandhinagar, Gujarat 382721

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PRODUCT SPECIFICATION SHEET

FISH OIL 18/12 EE (Ethyl Ester)

Product Name	FISH OIL 18/12 EE (Ethyl Ester)	**Document No.**	INFY/SPEC/FO-EE/001
Chemical Form	Ethyl Ester (EE)	**Revision No.**	00
Effective Date	27-Sep-2026	**Next Review Date**	26-Sep-2028

A. CHARACTERS & IDENTIFICATION

S. No.	Test Parameter	Specification / Acceptance Criteria	Method
Characters			
1	Appearance	**Light yellow liquid.**	Ph. Eur. 11
2	Odour	**Slight fish-like odour**	Ph. Eur. 11
3	Solubility	**Practically insoluble in water, very soluble in acetone, in ethanol (96 percent), in heptane and in methanol.**	Ph. Eur. 11
Identification			
4	Identification	**1. Peak retention time of EPA and DHA gas chromatography meets the standard. 2. EPA, DHA, Total Omega-3 content meets the standard.**	USP 401
5	Stearin	**Clear and transparent at 0°C for 3h**	Ph. Eur.
6	Colour	**Max. 6 Gardner**	In-house

B. ASSAY

S. No.	Test Parameter	Specification / Acceptance Criteria	Method
EPA (C20:5 n3)			
7	EPA – Area %	**A% Min. 18.0**	USP 401
8	EPA – as Ethyl Ester	**Min. 160.0 mg/g as EE**	USP 401
9	EPA – as Free Fatty Acid	**Min. 150.0 mg/g as FFA**	USP 401
DHA (C22:6 n3)			
10	DHA – Area %	**A% Min. 12.0**	USP 401
11	DHA – as Ethyl Ester	**Min. 105.0 mg/g as EE**	USP 401
12	DHA – as Free Fatty Acid	**Min. 100.0 mg/g as FFA**	USP 401
Total Omega-3			
13	Total Omega-3 – Area %	**A% Min. 35.0**	USP 401
14	Total Omega-3 – as Ethyl Ester	**Min. 315.0 mg/g as EE**	USP 401
15	Total Omega-3 – as Free Fatty Acid	**Min. 288.0 mg/g as FFA**	USP 401

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C. PHYSICO-CHEMICAL PARAMETERS

S. No.	Test Parameter	Specification / Acceptance Criteria	Method
16	Moisture and Volatiles	**Max. 0.1 %**	In-house
17	Absorbance	**Max. 0.55 @ 233 nm**	USP 401
18	Acid Value	**Max. 1.0 mgKOH/g**	USP 401
19	Peroxide Value	**Max. 3.5 meq/kg**	USP 401
20	Anisidine Value	**Max. 17.0**	USP 401
21	TOTOX	**Max. 23.0**	2PV + p-AV
22	Oligomers and Partial Glycerides	**Max. 7.0 %**	Ph. Eur. 2.2.30
23	Iodine Value	**Min. 140 g/100g**	USP 401
24	Unsaponifiable Matters	**Max. 1.5 %**	Ph. Eur. 2.5.7
25	*Cholesterol	**Max. 10.0 mg/g**	USP 401
26	*Residual Solvents (Ethanol)	**Max. 0.5 %**	In-house

D. CONTAMINANTS

S. No.	Test Parameter	Specification / Acceptance Criteria	Method
Inorganic Impurities			
27	Arsenic	**Max. 0.1 ppm**	External
28	Lead	**Max. 0.1 ppm**	External
29	Mercury	**Max. 0.1 ppm**	External
30	Cadmium	**Max. 0.1 ppm**	External
Pesticide Residue			
31	DDT (sum: o,p' + p,p')	**Max. 0.05 ppm**	External
32	DDD (sum: o,p' + p,p')	**Max. 0.05 ppm**	External
33	DDE p,p'	**Max. 0.05 ppm**	External
34	HCB	**Max. 0.05 ppm**	External
Environmental Contaminants			
35	*Benzo(a)pyrene	**Max. 2.0 ppb**	External
36	*PAH 4 (Sum)	**Max. 10.0 ppb**	External
37	*Dioxin + Furan	**Max. 1.0 pg WHO-TEQ/g**	External
38	*Dioxin-like PCBs	**Max. 3.0 pg WHO-TEQ/g**	External
39	*Dioxin + Furan + Dioxin-like PCBs	**Max. 3.0 pg WHO-TEQ/g**	External
40	*PCBs	**Max. 0.09 ppm**	External
Glycidol			
41	3-MCPD	**Max. 2.5 mg/kg**	In-house
42	Glycidol	**Max. 1.0 mg/kg**	In-house

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E. *MICROBIAL LIMITS			
S. No.	**Test Parameter**	**Specification / Acceptance Criteria**	**Method**
43	Aerobe	**Max. 1000 cfu/ml**	In-house
44	Yeasts and Molds	**Max. 100 cfu/ml**	In-house
45	Escherichia coli	**Absent in 10 ml**	In-house
46	Salmonella	**Absent in 10 ml**	In-house
47	S. aureus	**Absent in 10 ml**	In-house
48	P. aeruginosa	**Absent in 10 ml**	In-house

NOTES, PACKING & STORAGE	
Note	*Symbol items are skip tested 3 times per year. Tocopherol is added according to the customer's request.
Total Omega-3 includes	EPA, DHA, C18:3n3, C18:4n3, C20:4n3, C21:5n3, C22:5n3
Packing & Storage	190 kg per steel drum under N_2; keep in original packing; store in a cool and dry place
Shelf Life	24 months in suggested storage condition

SPECIFICATION APPROVAL			
	PREPARED BY	**REVIEWED BY**	**APPROVED BY**
Department	Quality Control	Quality Assurance	Head – Quality Assurance
Name			
Signature & Stamp		INFY LIFE SCIENCE SPECIFICATION APPROVED QUALITY ASSURANCE DEPT.	INFY LIFE SCIENCE AHMEDABAD
Date			

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