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 TG (Triglyceride)

Product Name	FISH OIL 18/12 TG (Triglyceride)	**Document No.**	INFY/SPEC/FO-TG/001
Chemical Form	Triglyceride (TG)	**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	**Pale yellow liquid.**	Ph. Eur. 11
2	Solubility	**Practically insoluble in water, very soluble in acetone and in heptane, slightly soluble in anhydrous ethanol.**	Ph. Eur. 11
Identification			
3	Identification	**1. Peak retention time of EPA and DHA gas chromatography meets the standard. 2. EPA, DHA, Total Omega-3 content meets the standard.**	Ph. Eur. 2.4.29
4	Stearin	**Clear and transparent at 0°C for 3h**	Ph. Eur. 11
5	Colour	**Max. 6 Gardner**	Internal

B. ASSAY

S. No.	Test Parameter	Specification / Acceptance Criteria	Method
EPA (C20:5 n3)			
6	EPA – Area %	**A% Min. 18**	Ph. Eur. 2.4.29
7	EPA – as Triglyceride	**Min. 160 mg/g as TG**	Ph. Eur. 2.4.29
8	EPA – as Free Fatty Acid	**Min. 155 mg/g as FFA**	Ph. Eur. 2.4.29
DHA (C22:6 n3)			
9	DHA – Area %	**A% Min. 12**	Ph. Eur. 2.4.29
10	DHA – as Triglyceride	**Min. 105 mg/g as TG**	Ph. Eur. 2.4.29
11	DHA – as Free Fatty Acid	**Min. 100 mg/g as FFA**	Ph. Eur. 2.4.29
Total Omega-3			
12	Total Omega-3 – Area %	**A% Min. 35**	Ph. Eur. 2.4.29
13	Total Omega-3 – as Triglyceride	**Min. 315 mg/g as TG**	Ph. Eur. 2.4.29
14	Total Omega-3 – as Free Fatty Acid	**Min. 302 mg/g as FFA**	Ph. Eur. 2.4.29

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C. PHYSICO-CHEMICAL PARAMETERS

S. No.	Test Parameter	Specification / Acceptance Criteria	Method
15	Moisture and Volatiles	**Max. 0.1 %**	Internal
16	Absorbance	**Max. 0.70 @ 233 nm**	Ph. Eur. 2.2.25
17	Acid Value	**Max. 1.0 mgKOH/g**	Ph. Eur. 2.5.1
18	Peroxide Value	**Max. 3.5 meq/kg**	Ph. Eur. 2.5.5
19	Anisidine Value	**Max. 17.0**	Ph. Eur. 2.5.36
20	TOTOX	**Max. 23.0**	2PV + p-AV
21	Oligomer	**Max. 1.5 %**	Ph. Eur. 2.2.30
22	TG (Triglycerides)	**Min. 60 %**	Ph. Eur. 2.2.30
23	Partial Glycerides	**Max. 40 %**	Ph. Eur. 2.2.30
24	Iodine Value	**Min. 140 g/100g**	USP 401
25	Unsaponifiable Matters	**Max. 1.5 %**	Ph. Eur. 2.5.7
26	*Cholesterol	**Max. 10.0 mg/g**	Ph. Eur. 2.4.32
27	*Residual Solvents (Ethanol)	**Max. 0.1 %**	Internal

D. CONTAMINANTS

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

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E. *MICROBIAL LIMITS			
S. No.	**Test Parameter**	**Specification / Acceptance Criteria**	**Method**
42	Aerobic Plate Count	**Max. 1000 cfu/ml**	Internal
43	Yeasts and Molds	**Max. 100 cfu/ml**	Internal
44	E. coli	**Absent in 10 ml**	Internal
45	Salmonella	**Absent in 10 ml**	Internal
46	S. aureus	**Absent in 10 ml**	Internal
47	P. aeruginosa	**Absent in 10 ml**	Internal

NOTES, PACKING & STORAGE	
Note	*Symbol items are skip tested 3 times per year. Tocopherols are 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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