

Omega 3 Odourless Fish Oil 1000mg Soft Gel Capsules

Origin: Australia



1. General Specification

No.	Fields	Specification	Reference
1.1	Dosage form	Capsule, soft gel.	
1.2	Route of Administration	Oral	
1.3	Physical appearance	20 minim oblong shaped clear soft gel capsule with vanilla odor containing light yellow coloured oil.	
1.4	Fill weight	1003 mg \pm 7.5%	In house
1.5	Total weight	1450 mg \pm 10%	In house
1.6	Uniformity of Mass	Complies to Current Therapeutic Goods Order	TGO78
1.7	Disintegration	Not more than 30 minutes.	BP.

2. Master Formulation

No.	Active Ingredient	RM Code	Label claim mg/capsule	Actual mg/capsule	Overage % claim	Release limit (%)	Reference standard
	Fish oil - natural	OL030	1000	1000		—	—
2.1	<i>Equiv. Eicosapentaenoic acid (EPA) (A%)</i>		180	—	—	NLT90 [^]	
	<i>Equiv. Docosahexaenoic acid (DHA)(A%)</i>		120	—	—	NLT90 [^]	BP.
	<i>Equiv. Omega-3 Marine Triglycerides</i>		300	—	—	QBI.	
	Ingredient weight			1000			

[^] Bulk oil is tested and then quantified by input.

No.	Excipient	RM Code	Quantity mg/capsule	Actual mg/capsule	Overage % claim	Release limit (%)	Reference standard
	d-alpha-Tocopherol		0.67				
2.2	<i>From d-alpha Tocopherol 1000 IU/g</i> <i>Contains Soya oil as excipient</i>	OL077	1	1	—	—	BP.
2.3	Lemon oil	OL013	1.4	1.4	—	—	BP.
2.4	Lime oil distilled	OL014	0.6	0.6	—	—	Manuf.
	Excipients weight		3.0				

No.	Capsule shell	RM Code	Quantity mg/capsule	Actual mg/capsule	Overage % claim	Release limit (%)	Reference standard
2.5	Gelatin	EX006	q.s.	—	—	—	BP.
2.6	Glycerol	EL001	q.s.	—	—	—	BP.
2.7	Vanillin	FL001	q.s.	—	—	—	BP.
2.8	Water-purified	ZZ001	q.s.	—	—	—	BP.
	Capsule weight		447				

3. Fill Weight & Total Weight

No.	Item	Weight mg/capsule	Release limit (mg)	Reference standard
3.1	Active ingredients	1000	—	—
3.2	Excipients	3.0	—	—
	Fill Weight	1003	928 – 1078	In house
3.3	Capsule weight	447	—	—
	Total weight	1450	1305 – 1595	In house

4. TSE Assessment (Transmissible Spongiform Encephalopathy)

No.	Item	Specific Animal Ingredient	Statement
4.1	TSE assessment required	Gelatin	TSE free
4.2	TGA preclearance number	–	–

5. Microbial Release Limits

No.	Item	Release limit	Reference standard
5.1	Total Viable Count (TVC)	NMT. 1×10^4 cfu/g	TGO77
5.2	Yeast and Mould Count	NMT. 1×10^2 cfu/g	TGO77
5.3	Bile-tolerant Gram negative bacteria	NMT. 1×10^2 cfu/g	TGO77
5.4	Salmonella	Not detected/10g	TGO77
5.5	Escherichia coli	Not detected/g	TGO77
5.6	Staphylococcus aureus	Not detected/g	TGO77

The first 3 batches will be microbiologically tested for finished products to meet TGO77 and then as part of a rotational testing program 1 batch in every 10th batch manufactured will be tested thereafter.

6. Product Stability Information

No.	Item	Specification
6.1	Shelf life	Sponsor
6.2	Storage temperature	Store below 25°C.
6.3	Storage condition	Store away from direct heat & sunlight

Expiry date (3) years from date of manufacture

7. GMO Status and Gelatin Statement

7.1	GMO status - free.
7.2	Gelatin from bovine hide/bone and sourced from New Zealand, Australia, Brazil, South Korea, USA, Argentina and China.

"BP" = British Pharmacopoeia; "BHP" = British Herbal Pharmacopoeia; "USP" = United States Pharmacopoeia;
"EP" = European Pharmacopoeia; "BPC" = British Pharmacopoeia Codex; "Manuf." Manufacturer's specification;
"TGA" = Therapeutic Goods Administration; "MI" = Merck Index; "FCC" = Food Chemicals Codex; "CI" = Colour Index.
"QBI" = Quantified by Input, Refer to the Australian Department of Health and Ageing Therapeutic Goods
Administration's document "Guidance on the Use of the term 'Quantified by Input' for Complementary Medicines".
Please note that all pharmacopoeia referenced are current edition, unless otherwise stated.

Release limit test may be conducted by contract laboratories:

Ferngrove Pharma Aust P/L , 5 Ferngrove Place, South Granville, NSW2142- Chemical & Physical testing (MI-19092007-LI-002109-11)

Naturalab Pty Ltd 111 Stephen Road,Botany NSW 2019 - Chemical & Physical testing (TGA No. MI-20062007-LI-001909-11)

Merieux NutriSciences(Silliker) 391 Park Road, Regents Park,NSW 2143 - Microbial testing (TGA No. MI-04072005-LI-00664-2)

AMS Laboratories Pty Ltd 8 Rachael Close , Silverwater NSW 2128 - Microbial testing (TGA No : MI-15112007-LI-002191-11)

Southern Cross Plant Science T Block Level 3, Military Road, Lismore, NSW,2480 - Chemical Testing (TGA No:181048)