Compositional guideline for Squid oil

Squid oil (ABN)

Definition of the ingredient

Purified, winterised and deodorised fatty oil obtained from the body of squid (species of order Teuthida, class Cephalopoda). Suitable antioxidants may be added.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Pale yellow clear liquid
Characteristics		
Solubility	BP (General notice)	Practically insoluble in water, very soluble in acetone and in heptane, slightly soluble in anhydrous ethanol
Absorbance	Ph Eur method 2.2.25	Not more than 0.50 at 233 nm
Identification		
EPA and DHA	Ph Eur method 2.4.29	The peaks due to EPA and DHA methyl esters in the chromatogram obtained with test solution (a) match the retention times of the corresponding peaks in the chromatograms obtained with reference solution (a_1) and reference solution (a_2)

Test	Method reference	Acceptance criteria
Composition of fatty acids	Ph Eur method 2.4.29	The fatty acids profile obtained from the chromatogram of the sample is similar to that obtained in the chromatogram of the reference standard[1]
Assay		
EPA as triglycerides	Ph Eur method 2.4.29	Not less than 9.0 % w/w
DHA as triglycerides	Ph Eur method 2.4.29	Not less than 18.0 % w/w
Total omega-3 acids as triglycerides	Ph Eur method 2.4.29	Not less than 30.0 % w/w
Notes		
1. In particular, the pattern in the group of C20 acids in the chromatogram comprises the following relative proportions: C20:0 (minor), C20:1(n-11) (major), C20:1(n-9) (major), C20:1(n-7) (minor).		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues	Ph Eur method 2.8.13	Complies
Other organic or inorganic impurities or toxins		
Dioxins, furans and polychlorinated biphenyls (PCBs)	USP monograph for 'Fish oil containing Omega-3 Acids'	Complies
Acid value	Ph Eur method 2.5.1	Not more than 1.5
Anisidine value	Ph Eur method 2.5.36	Not more than 15.0
Unsaponifiable matter	Ph Eur method 2.5.7	Not more than 5.0 % w/w

Test	Method reference	Acceptance criteria
Peroxide value	Ph Eur method 2.5.5 (Method A)	Not more than 5.0
Oligomers	Ph Eur method 2.2.30[2]	Not more than 1.5%
Stearin	AOCS Method Cc11-53	10 mL remains clear after cooling at 0°C for 3 h
Incidental metals and non-metals		
While ingredient manufacturers are encouraged to include limits for Incidental metals and non-metals, it is the product into which those substances are formulated that contains the ingredient, alone or in combination with other ingredients, must comply with the acceptance criteria set in the United States Pharmacopeia - National Formulary (USP-NF) general chapter '<2232> Elemental Contaminants in Dietary Supplements'. When testing is performed at the raw material stage, calculation of the total daily exposure in the finished product should be performed. This calculation is based on the quantity of each ingredient present in the product, the maximum potential contamination given the proposed limits for each raw material and the daily dose of the product.		
Microbiology		
While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is subject to a legally binding set of criteria. The Therapeutic Goods Order No. 77 *'Microbiological Standards for Medicines'* mandates that any finished product that contains the ingredient, alone or in combination with other ingredients, must comply with the microbial acceptance criteria set by Clause 9 of the Order.		
Notes		
2. Using the test method described in the BP monograph for *Fish Oil, Rich in Omega-3-Acids*		

Key to abbreviations:

AOCS = American Oil Chemist's Society

BP = British Pharmacopoeia

DHA = Docosahexaenoic acid

EPA = Eicosapentaenoic acid

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopeia