

**Certificate of Analysis**

Product Name: NucleVital® Q10 Complex – FSMP
(Food for Special Medical Purpose)
Product: Nucle Vital® Q10 softgels
Product No.: MNSG-307 – Blister Cards
Batch Number: SB006451C 12 2018
Expiration: December 2018

General	Manufacturing Specification	Result	Methods
Pharmaceutical Form	Oblong shaped softgels containing reddish colored oily suspension, beige color one side and green color other side	Conforms	Observation
Capsule size and shape	20 Oblong	Conforms	Observation
Average Fill Weight	1080 mg +/- 5%	1082	USP <2091>
Disintegration/Rupture time	Max. 15 minutes	2 min.	USP <2040>
Acid Value ¹	Max. 3 mg KOH/g	1.0	Ph.Eur. 2.5.1
Peroxide Value ¹	Max. 5 meq/kg	2	AOCS Cd 8-53
Peroxide Value Finished Softgels ⁶	Report	21	AOCS Cd 8-53
Anisidine Value ¹	Max. 20	Passed	Ph.Eur.2.5.36
Lead ¹	Max. 0.1 mg/kg	Passed	External laboratory*
Cadmium ¹	Max. 0.1 mg/kg	Passed	External laboratory*
Mercury ¹	Max. 0.1 mg/kg	Passed	External laboratory*
Arsenic (inorganic) ¹	Max. 0.1 mg/kg	Passed	External laboratory*
PCBs (209 Congeners) ¹	Max. 0.09 mg/kg	Passed	External laboratory*
Sum of Dioxins & Furans (17) ¹ - TEQ ²	Max. 2 pg/g	Passed	External laboratory*
Sum of Dioxins & Furans and Dioxin like PCBs ¹ - TEQ ²	Max. 3 pg/g	Passed	External laboratory*

Microbiological Standard	Manufacturing Specification	Result	Methods
Total Plate Count	Does not exceed 3,000 cfu/g	Conforms	USP<2021> or Soleris**
Total Mold & Yeast Count	Does not exceed 300 cfu/g	Conforms	USP<2021> or Soleris**
Salmonella	Negative/10g	Conforms	USP<2022>
E. Coli	Negative/10g	Conforms	USP<2022> or Soleris**
Staphylococcus Aureus	Negative/10g	Conforms	USP<2022> or Soleris**

*See attached Analytical Report(s).

** The Soleris Method is AOAC certified



Ingredients	Manufacturing Specification per 1 softgel	Result	Methods
Norwegian Virgin Salmon Oil w/Natural Lemon Flavor and Proprietary Antioxidant Blend ³	676 mg +/- 5%	678 mg	Input
EPA (as TG) ⁴	45 – 75 mg	47 mg	Ph.Eur. 2.4.29/GOED
DHA (as TG) ⁴	55 – 75 mg	72 mg	Ph.Eur. 2.4.29/GOED
Other Omega-3s (as TG) ⁴	Report	61 mg	Ph.Eur. 2.4.29/GOED
Additional Omega-3 ⁵ (as TG) ⁴	25 – 75 mg	80 mg	Ph.Eur. 2.4.29/GOED
Total Omega-3s (as TG) ⁴	125 – 225 mg	180 mg	Ph.Eur. 2.4.29/GOED
CoQ10 as Ubiquinone	50 mg	52.5 mg	Input
Mixed Natural Tocopherols	25 mg	25 mg	Input
d-alpha Tocopherol	5 mg	5.7 mg	Input
Lycopene	7.5 mg	7.5 mg	Input
Lutein (free)	5 mg	6.4 mg	Input
Zeaxanthin (free)	1 mg	1.2 mg	Input
Astaxanthin	2.5 mg	2.5 mg	Input
L-Selenomethionine	55 mcg	75 mcg	Input
Vitamin D (as D ₃ Cholecalciferol)	500 IU	675 IU	Input
Additional Ingredients	Beeswax	Conforms	Input

Ingredients	Manufacturing Specification	Result	Methods
Shell Ingredients	Gelatin, Glycerin, Annatto Extract, Titanium Dioxide, Chlorophyll and Purified Water	Conforms	Input
Shell Hardness	Regular	Conforms	Input
Flavor Coating	No	Conforms	Input

¹ Analysis performed on fish oil before the addition of other ingredients

² Toxicity Equivalents according to WHO

³ **Additives:** A proprietary natural antioxidant blend consisting of Natural Tocopherols, Rosemary Extract, and Ascorbyl Palmitate has been added, as has proprietary natural lemon flavoring.

⁴ Measured as Triglyceride. Any third party test result must be based on a laboratory using the CRN/GOED or European Pharmacopeia method, non-modified. Analytical Results using AOAC, AOCS, USP or other methods, will not be recognized in a possible conflict of results.

⁵ Additional Omega-3s include EPA and DHA above minimum specification as well as Other Omega-3s from line above.

⁶ Elevated result due to matrix interference by CoQ10 on the analytical test.

Lisa McAteer

Mt. Bethel PA August 21, 2017

Lisa McAteer for MarineIngredients

Place

Date