

**Certificate of Analysis**

PRODUCT NAME: **BioCardine® Omega-3 –FSMP  
(Food for Special Medical Purpose)**  
 PRODUCT: **Fish Oil ~ Ethyl Ester Concentrate  
Oil from sardines and anchovies from the South Pacific**  
 PRODUCT NO.: **MNSG-296 – Blister Cards**  
 BATCH NO: **1311132 11 2017**  
 EXPIRATION: **November 2017**

General	Manufacturing Spec.	Result	Methods
Pharmaceutical Form	Clear soft gelatin capsules containing a light golden oil	Conforms	Observation
Capsule size and shape	20 oblong	Conforms	Observation
Average Fill Weight	1106 mg +/- 5%	1099 mg	ITG ATM 030
Disintegration/Rupture time	Max. 15 minutes	Conforms	BP/EP requirements
Acid Value	Max. 3 mg KOH/g	0.6	031/Ph.Eur.Supp14.3 01/2003
Peroxide Value <sup>1</sup>	Max. 5.0 meq/kg	1.89	GC & Intl Standards
Anisidine Value <sup>1</sup>	Max. 20	15	016
Lead	Max. 0.1 mg/kg	Passed	§64 LFGB L00.00-19/3 AAS-Gr.
Cadmium	Max. 0.1 mg/kg	Passed	§64 LFGB L00.00-19/3, AAS-Gr.
Arsenic (inorganic)	Max. 0.1 mg/kg	Passed	Analog § 64 LFGB L 00.00-19/3, AAS-Gr.
Mercury	Max. 0.1 mg/kg	Passed	§64 LFGB L00.00-19/4, AAS-cold vapor
Marker PCBs (7) <sup>2</sup>	Max. 0.09 mg/kg	Passed	GC/HRMS
Sum of dioxins, furans and dioxin-like PCBs (WHO-PCDD/F – PCB-TEQ) <sup>2</sup>	Max. 10 pg/g	Passed	HRGC-HRMS EN 1948 modified, HRCG-HRMS

Microbiological Standard	Manufacturing Spec.	Result	Methods
Total Plate Count	Max. 3,000 cfu/g	<10	USP/FDA-BAM
Total Mold & Yeast Count	Max. 300 cfu/g	<10	USP/FDA-BAM
Salmonella	Negative/10g	Neg.	USP/FDA-BAM
E. Coli	Negative/10g	Neg.	USP/FDA-BAM
Staphylococcus Aureus	Negative/10g	Neg.	USP/FDA-BAM



Ingredients	Manufacturing Spec.	Result	Methods
Fish Oil – Ethyl Ester w/natural Lemon Flavor & Proprietary Antioxidant Blend <sup>3</sup>	1106 mg +/- 5%	1100 mg	Input
EPA (as EE) <sup>4</sup>	330 mg	339 mg	Ph.Eur.2.4.29/CRN Monogr.06
DHA (as EE) <sup>4</sup>	220 mg	237 mg	Ph.Eur.2.4.29/CRN Monogr.06
Other Omega-3 (as EE) <sup>4</sup>	50 mg	120 mg	Ph.Eur.2.4.29/CRN Monogr.06
Total Omega-3 Fatty Acids (as EE) <sup>4</sup>	600 mg	696 mg	Ph.Eur.2.4.29/CRN Monogr.06

<sup>1</sup> Analyzed before adding the lemon oil.

<sup>2</sup> Toxicity Equivalents according to WHO

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

<sup>4</sup> Measured as Ethyl Esters. Any third party test result must be based on a laboratory using the CRN or European Pharmacopeia method. Results from other methods, such as AOAC, AOCS, USP or other methods, will not be recognized in a possible conflict of results.

*Lisa McAteer*

Mt. Bethel, PA January 15, 2016

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*Lisa McAteer for Marine Ingredients*

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*Place*

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*Date*