

Certificate of Analysis

Company Name:	Biotics Research Corporation	Product Code(s):	BFP 1417
Product Name:	Biomega-1000		
Batch / Lot #	208713	Expiration Date:	06-OCT-24
Product Description:	Soft gelatin capsule	Size /Form:	Oblong
Appearance / Color:	Clear to light yellow	Avg. Capsule Weight (Gross):	1,519 mg
Packaging:	White HDPE w/PS liner and safety neckband		

<u>Active Ingredient:</u>	<u>Each Capsule contains*:</u>	<u>Claim</u>	<u>Result</u>	<u>Method</u>
Omega-3 Fatty Acids	1,143 mg	1,143 mg	1,143 mg	Input*

*as declared by manufacturer

	<u>Evaluations</u>	<u>Specifications</u>	<u>Results</u>
Identification:		Must Conform	pass
Disintegration:		<30 minutes	pass
Residual Solvents:		ICH Q3C	pass
Peroxide Value (PV)		<5 meq/kg	2.92 meq/kg
Anisidine Value (AV)		< 20	
TOTOX		< 26	

Heavy Metals⁽¹⁾:

Arsenic	< 0.14 µg/kg b.w./day	< 0.14 µg/kg b.w./day
Cadmium	< 0.09 µg/kg b.w./day	< 0.09 µg/kg b.w./day
Lead	< 0.14 µg/kg b.w./day	< 0.14 µg/kg b.w./day
Mercury	< 0.29 µg/kg b.w./day	< 0.29 µg/kg b.w./day

Microbiology⁽²⁾:

Total Aerobic Microbial Count (TAMC)	NMT 10 ⁵ CFU/g	pass
Total Combined Yeast and Mold Count (TYMC)	NMT 10 ³ CFU/g	pass
Escherichia coli	Negative	pass
Listeria	Negative	pass
Salmonella	Negative	pass
Staphylococcus aureus	Negative	pass

⁽¹⁾ This calculation assumes a body weight of 70 kg for an average adult. If the dosage is intended for children, the appropriate body weight for the age of the child in the recommended use should be used.


⁽²⁾ USP <2023> Negative means < 1 X 10¹ CFU/g or CFU/mL for Total viable aerobic count, Enterobacteriaceae and Yeast and Mould count, not detected in 10 g or 10 mL for Salmonella spp. and not detected in 1 g or 1 mL for E. coli, Listeria and S. aureus. cfu refers to Colony Forming Units per gram

Appearance:

Color	normal
Fill volume	normal

SEP 23 2022

Manufactured Date



Prepared by/Date



QA Review by/Date