

Certificate of Analysis

Company Name:	Biotics Research Corporation	Product Code(s):	BFP 031; 1417
Product Name:	Biomega-1000	Expiration Date:	23-DEC-21
Batch / Lot #	912084	Size /Form:	#24 oblong
Product Description:	Soft gelatin capsule	Avg. Capsule Weight:	2,056 mg
Appearance / Color:	Pinkish Red		
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>
Vitamin E		4 mg	pass	typical
Omega-3 Fatty Acids		1,143 mg	pass	typical

*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	meq/kg
Anisidine Value (AV)		< 20	
TOTOX		≤ 26	

<u>Heavy Metals⁽¹⁾:</u>			
Arsenic		< 0.14 µg/kg b.w./day	µg/kg b.w./day
Cadmium		< 0.09 µg/kg b.w./day	µg/kg b.w./day
Lead		< 0.14 µg/kg b.w./day	µg/kg b.w./day
Total Mercury		< 0.29 µg/kg b.w./day	µg/kg b.w./day

<u>Microbiology⁽²⁾:</u>		
Total Aerobic Microbial Count (TAMC)	NMT 10 ⁵ cfu/g	pass
Total Combined Yeast and Mold Count	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

DEC 23 2019

Manufactured Date

Prepared by/Date

m g p s 1/22/20

Brenda Beumald 1-27-20

QA Review by/Date