

Certificate of Analysis

Company Name:	Biotics Research Corporation	Product Code(s):	BFP 035; 1424
Product Name:	Biomega-500	Expiration Date:	2/21
Batch / Lot #	901097	Size /Form:	#14 oblong
Product Description:	Soft gelatin capsule	Avg. Capsule Weight:	1,076 mg
Appearance / Color:	Dark Amber		
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		2 mg	pass	typical
Omega-3 Fatty Acids *as declared by manufacturer		570 mg	pass	typical

	<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	pass
Anisidine Value (AV)		< 20	pass
TOTOX		< 26	pass

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

<u>Microbiology⁽²⁾:</u>			
Total Aerobic Count Plate (ACP)		NMT 10 ⁵ cfu/g	pass
Total Combined Yeast and Mold Count		NMT 10 ³ cfu/g	pass
Escherichia coli 0157:H7		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

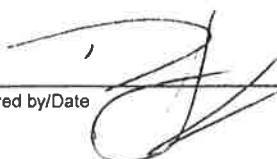
Appearance:

Color	normal
Fill volume	normal

FEB 15 2019

Manufactured Date

Prepared by/Date

 2/15/19

QA Review by/Date

 2-15-19