

Certificate of Analysis

Company Name:	Biotics Research Corporation		
Product Name:	Flax Seed Oil	Product Code(s):	1405
Batch / Lot #	805002	Expiration Date:	10/20
Product Description:	Soft gel capsule	Size /Form:	#20 oblong
Appearance / Color:	Dark amber-black	Avg. Capsule Weight:	1,496 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>
Flax Seed Oil		1,000 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
<u>Heavy Metals⁽¹⁾:</u>		
Arsenic	< 0.14 µg/kg b.w./day	pass
Cadmium	< 0.09 µg/kg b.w./day	pass
Lead	< 0.29 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

Patricia Dyles 5/10/18
Prepared by/Date

M. S. S. 5-10-18
QA Review by/Date