

**CERTIFICATE OF ANALYSIS**

Product Number: MSU1181-BO120  
Product Description: Ocean Blue 2100 Softgel  
Customer: OceanBlue®  
Customer Item No.: OBP-2100-120  
Bulk Batch No.: 2009046 (L002194)

Batch No: 20H016  
Manufactured Date: August 03, 2020  
Test Date: October 29, 2020  
Expiration Date: 08/2023

Tests	Acceptance Criteria	Method	Results
Description	Clear transparent oblong soft gelatin capsule containing pale yellow liquid	STM001	Pass
Fill Weight	1351 mg ± 5%	USP <2091>	1357 mg
Weight Variation	Meets USP <2091>	USP <2091>	Pass
Average Total Weight	1911 mg ± 10%	USP <2091>	1924 mg
Rupture Test	Max. 15 Minutes	USP <2040>	2 minutes
EPA (as EE)	Min. 675 mg	STM067, GOED or equivalent	775 mg
DHA (as EE)	Min. 300 mg	STM067, GOED or equivalent	342 mg
Total Omega-3 (as EE)	Min. 1050 mg	STM067, GOED or equivalent	1201 mg
Arsenic (inorganic)	≤ 10 mcg/softgel	ICP-MS or equivalent	0 mcg/softgel
Cadmium	≤ 4.1 mcg/softgel	ICP-MS or equivalent	<0.5 mcg/softgel
Lead	≤ 0.5 mcg/softgel	ICP-MS or equivalent	<0.1 mcg/softgel
Mercury (total)	≤ 2.0 mcg/softgel	ICP-MS or equivalent	<0.2 mcg/softgel
Total Aerobic Bacterial Count	<1000 cfu/g	USP or equivalent	<1,000 cfu/g
Total Mold/Yeast Count	<100 cfu/g	USP or equivalent	<100 cfu/g
Enterobacteriaceae	<100 cfu/g	USP or equivalent	<100 cfu/g
<i>Escherichia coli</i>	Negative/10 g	USP or equivalent	Negative/10g
<i>Salmonella spp</i>	Negative/10 g	USP or equivalent	Negative/10g
<i>Staphylococcus aureus</i>	Negative/10 g	USP or equivalent	Negative/10g

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Tooling Size:	24 Oblong
Ingredients	Fish Oil EE; Gelatin, Bovine; Glycerin; Purified Water; Natural Orange Flavor.
Allergens:	None*
*Contains highly refined fish oil and highly refined soybean. Labeling exempt per US Food Allergen Labeling and Consumer Protection Act (FALCPA)	


Approvals: \_\_\_\_\_

Quality Control: 

Date: 10-29-20

Quality Assurance: 

Date: 10/30/20

	<b>PACKAGED FINISHED PRODUCT RELEASE CHECKLIST</b>	Lot # : <i>204016</i>
	Form QA-007-2, Revision 2	Code: <i>MSU1181-B0120</i>
	Effective Date: <b>AUG 19 2020</b>	Amount Released: <i>10,452</i>
		Page 1 of 1

Check Mark as completed:	Yes	No	N/A
<b>1) Batch Record Review</b>			
Each page checked for completeness	✓		
All in process check verified	✓		
All calculations and yield checked correct and within limits or investigation	✓		
Label Content and Accountability Verified, including PO #	✓		
Batch Signed and Reviewed by/Date <u><i>Galena 10/29/20</i></u>			
<b>2) COA Review</b>			
COA Product information (lot, code, expiration etc.) verified	✓		
COA criteria verified vs. current approved specifications	✓		
COA signed as QA Approved	✓		
<b>3) Finished Product Release</b>			
Investigations approved and acceptable for batch release; <b>Investigation numbers:</b>			✓
Deviations approved and acceptable for batch release; <b>List numbers:</b>			✓
Batch Release	✓		
Batch Rejected; If "Yes" list MDO#		✓	

Comments: *bulk 2009006, 120 ct*

Checklist Completed By/Date: *Galena 10/30/20*