

 KD Nutra <small>Creating Health Solutions</small>	PACKAGED FINISHED PRODUCT RELEASE CHECKLIST	Lot #: VB220070
	Form QA-007-2, Revision 3	Code: MSU1181-BD120SP
	Effective Date: JAN 19 2022	Amount Released: 10234
		Page 1 of 1

Check Mark as completed:	Yes	No	N/A
1) Batch Record Review			
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>gms/20/22</u>			
2) COA Review			
COA Product information (lot, code, expiration etc.) verified	/		
COA criteria verified vs. current approved specifications	/		
COA signed as QA Approved	/		
3) Finished Product Release			
Investigations approved and acceptable for batch release; Investigation numbers:		/	
Deviations approved and acceptable for batch release; List numbers: Dev 7562	/		
Batch Release	/		
Batch Rejected; If "Yes" list MDO#		/	
4) Therapeutic Goods Administration compliance			
This certifies that documentation was reviewed by Authorized Person and found to comply with Marketing Authorization requirements and is acceptable to permit release.			
No changes occurred in the formulation of this lot from approved formulation			/
Executed batch record was reviewed, manufactured in accordance with procedures and the principles of cGMP and approved by QA			/
Product is on the APR schedule and signed annual APR was reviewed.			/

Comments: Bulk: VS220147, 120ct.

Checklist Completed By/Date: Released gms/20/22



2710 Progress Street, Vista, CA 92081
(760) 734-6800 Main • (760) 734-6565 Fax

Certificate of Manufacture

Product Code	Lot No.	Product Description
0372.1004.01	VB220070	EE Fish Oil (MSU1181-BO120)

The products specified above have been manufactured, tested and approved in accordance with 21 CFR Part 111 current Good Manufacturing Practices and Captek's Standard Operating Procedures. All procedures have been followed; all incoming materials have been evaluated and approved; all quality inspections have met specifications; all testing has been completed and approved; all documentation has been reviewed for completeness and accuracy; all discrepancies/deviations have been properly investigated, documented, and approved by the Quality Unit.

Approved by: *[Signature]* Date: 05-20-2022



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CERTIFICATE OF ANALYSIS

PRODUCT NAME:	OCEAN BLUE 2100. SG (MSU1181-BO120SP)		
PRODUCT CODE:	0372.1004.01		
LOT NUMBER:	VS220147		
CUSTOMER NAME:	KD Nutra		
BOTTLE JOB:	VB220070		
DESCRIPTION:	25 Oblong clear softgels containing pale yellow liquid		
MANUFACTURING DATE:	04/07/2022 ✓		DOSAGE FORM: Softgel
EXPIRATION DATE:	04/07/2025 ✓		

TEST ITEMS	SPECIFICATIONS	TEST METHODS	RESULTS
1. PHYSICAL:			
• Average Fill Weight	1351 mg ± 5%	Measure	1367.1 mg
• Average Total Weight	2015 mg ± 10%		2083.7 mg
• Weight Variation			
• Minimum Weight (% of the Average)	≥90%	USP <2091>	98.4%
• Maximum Weight (% of the Average)	≤110%		101.1%
• Disintegration Time (by Rupture Test)	NMT 15 minutes^	USP <2040>	7 Mins.
2. ACTIVE INGREDIENT (One Softgel contains):			
• Fish Oil (customer supplied)	≥ 1330.5 mg*		1359.8mg*
• EPA (as EE)	≥ 675 mg	CSI-QC-GC-102	733.37mg (by GC)
• DHA (as EE)	≥ 300 mg		331.5mg (by GC)
• Total Omega-3 (as EE)	≥ 1050 mg		1140.3mg (by GC)
3. IMPURITIES TEST:			
• Gluten Test	< 20 ppm	Eurofins	< 5ppm
4. MICROBIOLOGICAL TEST:			
• Total Aerobic Microbial Count	≤ 1000 cfu/g^	CSI-QC-MB-101/102	< 10cfu/g
• Total Yeasts and Molds	≤ 100 cfu/g^		< 10cfu/g
• <i>Enterobacteriaceae</i>	≤ 100 cfu/g^		< 10cfu/g
• <i>Salmonella spp</i>	Negative/10g^		Negative/10g
• <i>Staphylococcus aureus</i>	Negative/10g^		Negative/10g
• <i>E. coli</i>	Negative/10g^		Negative/10g
(Other Ingredient- Gelatin capsule (Bovine Gelatin, Glycerin and Purified Water) and Natural Flavor (from d-limonene).			

*Ensured by documented control.

^ At time of release

Prepared By: [Signature] Date: 05/17/22 Reviewed By: [Signature] Date: 05/17/22
 QC Scientist Susan Ho, QC Asst. Manager