BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Marine Collagen		
Product Code:	N/A		
Product type:	Capsule		
Color/Size/Shape	Clear-Clear size "00" veggie Capsule filled with white Color Powder.		
Product Packaging:	Bottles: 250 cc White HDPE 45/400 (not tall), CAP: 45/400 White Ribbed cap with HIS liner, Silica gel (0.5gram), Shrink band 66x28mm		
NPN	80132951		
Storage Conditions:	Store in a cool, dry place.		
Allergen(s)	**Yes** ■	**No** □	**If yes, list:** Fish Allergen
QA Approved By/Date:	Feb.24,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim (mg)**	**Tolerance limits**
Hydrolyzed Collagen (Fish-Skin, bone)	500.00	Not Assayed. Product is manufactured quantification by input to contain 500.00 mg of Hydrolyzed Collagen (Fish-Skin, bone)
List of Non-Medicinal Ingredients		
Hypromellose		

Manufacturing Date	Feb.24,2026	**Biowell Lot #**	022622
Expiry Date	JA-2028		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	Visual	Clear-Clear size "00" veggie Capsule filled with white Color Powder	Clear-Clear size "00" veggie Capsule filled with white Color Powder
Disintegration	USP <2040>	NMT 45 min	12 min
Target Net Content	Scale	500.00 mg	500.00 mg
Weight variation	USP <2091>	620.00 mg (573.50 – 666.50) mg	(573.50 – 666.50) mg
Locked Length	Measurement	Size "00": 23.4 ± 0.3 mm	(23.10 – 23.70) mm

Microbial-Tested on Finished Product			
Test	**Method**	**Parameter**	**Results**
Total Aerobic Microbial Count	<USP 2021>	NMT 1000 CFU/g	<10 CFU/g
Total Yeast & Mold	<USP 2021>	NMT 100 CFU/g	<10 CFU/g
Salmonella spp.	<USP 2022>	Absent in 10g	Absent
E. Coli	<USP 2022>	Absent in 10g	Absent
Staphylococcus aureus	<USP 2022>	Absent in 10g	Absent
Microbial tolerance (limits) as per USP<2023> Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements, and USP<1111>Microbiological Examination of Nonsterile Products: Acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use			

Heavy Metal-Tested on Finished Product			
Arsenic	USP<233>	<0.14 µg/kg b.w./day	<0.001 µg/kg b.w./day
Cadmium	USP<233>	< 0.09 µg/ kg b.w./day	<0.001 µg/kg b.w./day
Lead	USP<233>	< 0.14 µg/ kg b.w./day	0.001 µg/kg b.w./day
Mercury	USP<233>	< 0.29 µg/ kg b.w./day	<0.001 µg/kg b.w./day
Tolerance (limits) as per Appendix 3-General finished product specifications for NHP, Quality of NHP Guide			

Chemical- Tested on Finished Product			
Test	**Method**	**Parameter**	**Results**
Residual Solvents (Class III)	USP <467>	Total: < 5000 ppm (<0.5% v/v)	40 ppm (Refer to raw materials COAs)
Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >			

Product Disposition	Released ☑	Conditional Release ☐	Rejected ☐
QA Signature:	[signature]	Date:	MAR. 17, 2026