BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Zinc & Copper		
Product Code:	N/A		
Product type:	Capsule		
Color/Size/Shape	Clear-Clear size "0" vegi. Capsule filled with White Color Powder.		
Product Packaging:	Bottles: 200cc White 38/400 HDPE (not tall), Cap: White Color ribbed with HIS liner Lids 38/400, Desiccant: 0.5 gm Silica Gel, Shrink band 66x28mm		
NPN	80133530		
Storage Conditions:	Store in cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	, Jan.12,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim (mg)**	**Tolerance limits**
Copper (Copper Citrate)	1.00 mg	Not Assayed. Product is manufactured quantification by input to contain 1.00 mg of Copper (Copper Citrate)
Zinc (Zinc Citrate)	12.00 mg	Not Assayed. Product is manufactured quantification by input to contain 12.00 mg of Zinc (Zinc Citrate)
List of Non-Medicinal Ingredients		
Hypromellose, Microcrystalline cellulose, Silicon Dioxide		

Manufacturing Date	Jan.12,2026	**Biowell Lot #**	012620
Expiry Date	DE-2027		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Clear-Clear size "0" vegi. Capsule filled with White Color Powder**	Clear-Clear size "0" vegi. Capsule filled with White Color Powder
Disintegration	**USP <2040>**	**NMT 45 min**	06 min
Target Net Content	**Scale**	**365.00 mg**	365.00 mg
Weight variation	**USP <2091>**	**470.00 mg (434.75 - 505.25) mg**	(434.75 - 505.25) mg
Locked Length	**Measurement**	**Size "0": 21.60 ± 0.3 mm**	(21.30 – 21.90) 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**	0.002 µg/kg b.w./day
Lead	**USP<233>**	**< 0.14 µg/ kg b.w./day**	0.003 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)**	181 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:		**Date:**	MAR. 23, 2026