BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique Arginine		
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	80081995		
Storage Conditions:	Store in a cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Jan.21,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim (mg)**	**Tolerance limits**
L-Arginine	500.00 mg	Not Assayed. Product is manufactured quantification by input to contain 500.00 mg of L-Arginine
List of Non-Medicinal Ingredients		
Hypromellose		

Manufacturing Date	Jan.21,2026	**Biowell Lot #**	012632
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**	11 min
Target Net Content	**Scale**	**500.00 mg**	500.00 mg
Weight variation	**USP <2091>**	**605.00 mg (559.63 - 650.37) mg**	(559.63 - 650.37) 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**	<0.001 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)**	53.00 ppm (Refer to raw materials COAs)
Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >			

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Product Disposition	Released ☑	Conditional Release ☐	Rejected ☐
QA Signature:	[signature]	Date:	MAR. 09, 2026