BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique L-Glutamine (180 Capsules)		
Product Code:	70-0128		
Product type:	Capsule		
Color/Size/Shape:	Clear-Clear size "00" vegi. capsule filled with white powder.		
Product Packaging:	Bottle : 400cc White HDPE 45/400 Cap : White ribbed cap 45/400 Silica : 0.5g Shrink : 75mm x 28mm label : Adhesive matte printed label		
NPN	80142279		
Storage Conditions:	Store in a cool and dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Jun.24,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
L-Glutamine	650.0 mg	Not Assayed. Product is manufactured quantification by input to contain 650.0 mg of L-Glutamine
List of Non-Medicinal Ingredients		
Hypromellose, Silicon dioxide		

Manufacturing Date	Jun.24,2026	**Biowell Lot #**	BL062639
Expiry Date	MA-2029		

BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Clear-Clear size "00" vegi. capsule filled with white powder**	Clear-Clear size "00" vegi. capsule filled with white powder
Disintegration	**USP <2040>**	**NMT 45 min**	15 min
Target Net Content	**Scale**	**655.00 mg**	655.00 mg
Weight variation	**USP <2091>**	**775.00 mg (736.25 – 813.75) mg**	(736.25 – 813.75) mg
Locked Length	**Measurement**	**Size "00": 23.4 ± 0.3 mm**	(23.10 – 23.70) mm

Microbial Tests			
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 Tests			
Test	**Method**	**Parameter**	**Results**
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 Tests			
Test	**Method**	**Parameter**	**Results**
Residual Solvents (Class III)	**USP <467>**	**Total: < 5000 ppm (<0.5% v/v)**	120 ppm (Refer to raw materials COAs)
Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >			

BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Product Disposition	Released ☑	Conditional Release ☐	Rejected ☐
QA Signature:	[signature]	Date:	AUG. 12, 2026