BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique Creatine Monohydrate (500g)		
Product Code:	70-0141		
Product type:	Powder		
Color/Size/Shape:	Off-White to Creamish color powder		
Product Packaging:	Jar : 25 OZ White Jar 89/400 Cap : White ribbed cap 89/400 Silica : 5g Scoop : 7.5cc Long handle		
NPN	80133296		
Storage Conditions:	Store in cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Jul.07,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
Creatine Monohydrate	5.00 g	Not Assayed. Product is manufactured quantification by input to contain 5.00 g of Creatine Monohydrate
List of Non-Medicinal Ingredients		
N/A		

Manufacturing Date	Jul.07,2026	**Biowell Lot #**	BL072606
Expiry Date	JN-2029		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Off-White to Creamish color powder**	Off-White to Creamish color powder
Flavour	**Taste**	**Unflavored**	Unflavored
Net content (g/kg)	**Scale**	**500.00 g + 4% (500.00 – 520.00)g**	(500.00 – 520.00)g
Moisture Content (%)	**Moisture Analyzer**	**NMT 11%**	5.7%
Density (g/ml)	**USP <616>**	**0.30 – 0.40 (g/ml)**	0.36 g/ml
Tapped density (g/ml)	**USP <616>**	**0.35 – 0.45 (g/ml)**	0.41 g/ml

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 Testes			
Arsenic	**USP<233>**	**<0.14 µg/kg b.w./day**	<0.002 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)**	76 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:	AUG. 17, 2026