BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique CLA 1000 mg (60 Softgels)		
Product Code:	70-0165		
Product type:	Softgel		
Color/Size/Shape:	Clear oblong Softgel filled with yellow oily liquid		
Product Packaging:	Bottle : 200cc White HDPE 38/400 Cap : White ribbed 38/400 Silica : 0.5g Shrink : 66mm x 28mm label : Adhesive matte printed label		
NPN	80134781		
Storage Conditions:	Store in a cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Aug.06,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
CLA (Conjugated linoleic acid)	1000.00 mg	Not Assayed. Product is manufactured quantification by input to contain 1000.00 mg CLA (Conjugated linoleic acid)
List of Non-Medicinal Ingredients		
Gelatin, Glycerin, Water		

Packaging Date	Aug.06,2026	**Biowell Lot #**	BL082620
Expiry Date	JL-2028		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Clear oblong Softgel filled with yellow oily liquid**	Clear oblong Softgel filled with yellow oily liquid
Disintegration	**USP <2040>**	**NMT 30 min**	5 min
Target Net Content	**Scale**	**1000.00 mg**	1000.00 mg
Weight variation	**USP <2091>**	**1420.00 ± 7.5% (1313.50 - 1526.50) mg**	(1313.50 - 1526.50) mg

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**
Peroxide value (PV) *(Oils)*	**USP <401>**	**NMT 5 mEq/Kg**	1.2 mEq/Kg
Anisidine value (AV) *(Oils)*	**USP <401>**	**NMT 20 mEq/Kg**	6.0 mEq/Kg

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Total Oxidation (TOTOX) *(Oils)*	**USP <401>**	**NMT 26 mEq/Kg calculated as 2 x PV + AV**	7.0 mEq/Kg
Tolerance (limits) for Oxidative stability parameters in oils (marine oils, omega-3 fatty acids derived from marine oils and other oils), section 3.3.11, and Antibiotic residues in bee products (section 3.3.9), from Quality of NHP Guide			

Product Disposition	**Released** ☑	**Conditional Release** ☐	**Rejected** ☐
QA Signature:	[signature]	**Date:**	AUG. 24, 2026