BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique Ginkgo Biloba (90 Tablets)		
Product Code:	70-0139		
Product type:	Uncoated Tablet		
Color/Size/Shape:	Round shape, dark green color, uncoated tablet		
Product Packaging:	Bottle : 200cc White HDPE 38/400 Cap : White ribbed cap 38/400 Silica : 0.5g Shrink : 66mm x 28mm label :Adhesive matte printed label		
NPN	80091428		
Storage Conditions:	Store in cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Jul.06,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
Ginkgo Biloba (50:1,4500 mg) (25% Flavonoid Glycosides, 6% Terpene Lactones)	90.00 mg	Not Assayed. Product is manufactured quantification by input to contain 90.00 mg of Ginkgo Biloba (50:1,4500 mg) (25% Flavonoid Glycosides, 6% Terpene Lactones)
List of Non-Medicinal Ingredients		
Microcrystalline cellulose, Dicalcium phosphate, Croscarmellose sodium, Silicon dioxide Magnesium stearate, Stearic acid		

Manufacturing Date	Jul.06,2026	**Biowell Lot #**	BL072604
Expiry Date	JN-2029		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Round shape, dark green color, uncoated tablet**	Round shape, dark green color, uncoated tablet
Disintegration	**USP <2040>**	**NMT 45 min**	08 min
Thickness	**In-House**	**5.2 ± 5% mm (4.94 – 5.46) mm**	(4.94 – 5.46) mm
Friability	**USP < 1216>**	**NMT 1.0%**	0.18%
Hardness	**USP < 1216>**	**NLT 5.00 kgf**	NLT 5.00 kgf
Target Weight	**Scale**	**220.00 mg**	220.00 mg
Weight variation (mg)	**USP <2091>**	**220.00 ± 7.5% (203.50 – 236.50) mg**	(203.50 – 236.50) mg

Microbial-Testes			
Test	**Method**	**Parameter**	**Results**
Total Aerobic Microbial Count	**<USP 2021>**	**NMT 10000 CFU/g**	<10 CFU/g
Total Yeast & Mold	**<USP 2021>**	**NMT 1000 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**	<0.001 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			

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Chemical Tests			
Test	**Method**	**Parameter**	**Results**
Residual Solvents (Class III)	**USP <467>**	**Total: < 5000 ppm (<0.5% v/v)**	334 ppm (Refer to raw materials COAs)
Pesticides	**USP <561>**	**<LOQ outlined in Health Canada, Maximum residue limits (MRLS) set by the Pest Management Regulatory Agency (PMRA)**	Not detected (Refer to raw materials COAs)
Tolerance (limits) for Pesticides from USP <561>, Articles of Botanical Origins *Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >*			

Product Disposition	**Released** ☑	**Conditional Release** ☐	**Rejected** ☐
QA Signature:	[signature]	**Date:**	AUG. 17, 2026

Medicap Laboratories

CERTIFICATE OF ANALYSIS

Product Name: Biogenique Ginkgo Biloba

Batch/Lot No: 240916

Man. Date: Sep.2024 **Expiry Date:** Aug.2027

Each Tablet Contains: Ginkgo (Ginkgo biloba) (50:1 Extract, 4500 mg) (25% Flavonoid Glycosides, 6% Terpene Lactones): 90.0 mg

Other Ingredients: Colloidal silicon dioxide, Croscarmellose sodium, Magnesium stearate, Microcrystalline cellulose, Stearic acid.

Test	Method	Specifications	Result
Description	In-House	Round shape dark brown color uncoated tablet	Complies
Weight variation	USP <2091>	220.0 ± 7.5 % (203.5 mg to 236.5 mg)	222.00 mg
Friability	USP <1216>	< 1 %	0.23%
Thickness	USP <1217>	4.50 mm – 5.50 mm	4.92mm
Hardness	USP <1217>	NLT 05 kgf	07 kgf
Disintegration time	USP <701>	NMT 30 minutes	27 minutes
Microbial Test			
Total Plate count	USP<2021>	N.M.T 100,000 CFU/G	<10 CFU/G
Yeast & Mold	USP<2021>	N.M.T 1000 CFU/G	<10 CFU/G
E.coli	USP<2022>	Negative	Negative
Salmonella	USP<2022>	Negative	Negative
S.aureus	USP<2022>	Negative	Negative
Pseudomonas aeruginosa	USP<62>	Negative	Negative
Heavy Metal			
Arsenic	ICP-MS at Finished Product Stage	<0.14 µg/kg b.w./ day	0.001 µg/kg b.w./ day
Cadmium		<0.09 µg/kg b.w./ day	<0.001 µg/kg b.w./ day
Lead		<0.14 µg/kg b.w./ day	0.001 µg/kg b.w./ day
Mercury		<0.29 µg/kg b.w./ day	<0.001 µg/kg b.w./ day

Quality Approved: Foram Patel **Date:** Oct.28, 2024

This is to certify that Medicap Laboratories products are manufactured under strict GMP conditions