BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique Taurine		
Product Name:	Biogenique Taurine (90 Capsules)		
Product Code:	70-0132		
Product type:	Capsule		
Color/Size/Shape:	Clear-Clear size "0" vegi. capsule filled with white powder		
Product Packaging:	Bottle : 200cc White (Short) HDPE 38/400 Cap : White ribbed cap 38/400 Silica : 0.5g Shrink : 66mm x 28mm label : Adhesive matte printed label		
NPN	80142278		
Storage Conditions:	Store in a cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Jun.29,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
Taurine	500.00 mg	Not Assayed. Product is manufactured quantification by input to contain 500.00 mg of Taurine
List of Non-Medicinal Ingredients		
Hypromellose, Microcrystalline cellulose, Silicon dioxide, Magnesium stearate		

Manufacturing Date	Jun.30,2026	**Biowell Lot #**	BL062643
Expiry Date	MA-2029		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Clear-Clear size "0" vegi. capsule filled with white powder**	Clear-Clear size "0" vegi. capsule filled with white powder
Disintegration	**USP <2040>**	**NMT 45 min**	14 min
Target Net Content	**Scale**	**612.00 mg**	612.00 mg
Weight variation	**USP <2091>**	**717.00 mg (681.15 – 752.85) mg**	(681.15 – 752.85) mg
Locked Length	**Measurement**	**Size "0": 21.60 ± 0.3 mm**	(21.30 – 21.90) 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)**	237 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. 24, 2026

Medicap Laboratories

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Biogenique L-Taurine

Batch/Lot No: 240731

Man Date: Jul.2024 **Expiry Date**: Jun.2027

Each unit dose contains: 2-Aminoethanesulfonic acid (Taurine): 500.0 mg

Non-Medicinal Ingredient: Magnesium Citrate, Potassium chloride, Hypromellose.

Test	Method	Specifications	Result
Description	In-House	Clear- Clear size "0" vegi. Capsule filled with white color Capsules.	Complies
Weight variation	USP <2091>	717.0 ± 7.5 % (663.23mg to 770.78mg)	716.67 mg
Lock Length	In house	21.30 mm –21.90mm	Complies
Disintegration time	USP	NMT 30 minutes	07 minutes
Microbial Test			
Total Plate count	USP<2021>	NMT 100,000 CFU/g	<10 CFU/g
Yeast & Mold	USP<2021>	NMT 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.25, 2024

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