BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique Biotin (60 Tablets)		
Product Code:	70-0140		
Product type:	Uncoated Tablet		
Color/Size/Shape:	Round shaped white 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	80068482		
Storage Conditions:	Store in cool, dry temperature		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Jul.06,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
Biotin	500.00 mcg	Not Assayed. Product is manufactured quantification by input to contain 500.00 mcg of Biotin
List of Non-Medicinal Ingredients		
Microcrystalline cellulose, Dicalcium phosphate, Croscarmellose sodium, Silicon dioxide, Magnesium stearate		

Manufacturing Date	Jul.06,2026	**Biowell Lot #**	BL072605
Expiry Date	JN-2028		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Round shaped white color uncoated tablet**	Round shaped white color uncoated tablet
Disintegration	**USP <2040>**	**NMT 45 min**	01 min
Thickness	**In-House**	**4.92 ± 5% mm (4.68 – 5.16) mm**	(4.68 – 5.16) mm
Friability	**USP < 1216>**	**NMT 1.0%**	0.17 %
Hardness	**USP < 1216>**	**NLT 4.00 kgf**	NLT 4.00 kgf
Target Weight	**Scale**	**225.00 mg**	225.00 mg
Weight variation (mg)	**USP <2091>**	**225.00 mg ± 7.5% (208.13 – 241.88) mg**	(208.13 – 241.88) mg

Microbial-Testes			
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**	<0.001 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)**	272 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:		Date:	AUG. 17, 2026