BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Vitamin E		
Product Code:	N/A		
Product type:	Soft Capsule		
Color/Size/Shape:	Oval Softgel with clear Yellow Oily Fill		
Product Packaging:	Bottles: 200 cc White 38/400 HDPE (not tall) Cap: White color Lids 38/400 Silica gel 0.5g Shrink Band: 66x28mm		
NPN	80086931		
Storage Conditions:	Store in a cool and dry place.		
Allergen(s)	**Yes** ■	**No** □	**If yes, list:** Soy Allergen
QA Approved By/Date:	 Jan.07,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim (mg)**	**Tolerance limits**
Vitamin E (d-Alpha Tocopheryl acetate)	268.00 mg	Not Assayed. Product is manufactured quantification by input to contain 268.00 mg of Vitamin E (d-Alpha Tocopheryl acetate)) AT / 400 IU
List of Non-Medicinal Ingredients		
Gelatin, Glycerin, Soybean Oil.		

Packaging Date	Jan.07,2026	**Biowell Lot #**	PK012607
Expiry Date	DE-2027		

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Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Oval Softgel with clear Yellow Oily Fill**	Oval Softgel with clear Yellow Oily Fill
Disintegration	**USP <2040>**	**NMT 30 min**	06 min
Target Net Content	**Scale**	**428.00 mg**	428.00 mg
Weight variation	**USP <2091>**	**(628.00 mg ± 10%) (565.2-690.8) mg**	(565.2-690.8) mg

Microbial-Tested on Finished Product			
Test	**Method**	**Parameter**	**Results**
Total Aerobic Microbial Count	**<USP 2021>**	**NMT 1000 CFU/g**	800 CFU/g
Total Yeast & Mold	**<USP 2021>**	**NMT 100 CFU/g**	<10 CFU/g
Salmonella spp.	**<USP 2022>**	**Absent/10g**	Absent
E. Coli	**<USP 2022>**	**Absent/10g**	Absent
Staphylococcus aureus	**<USP 2022>**	**Absent/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-Tested on Finished Product			
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			

Product Disposition	**Released** ☑	**Conditional Release** ☐	**Rejected** ☐
QA Signature:	Shumaila Aftab	**Date:**	JAN. 22, 2026

Medicap Laboratories

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Biogenique Vitamin E

Batch/Lot No: PK241226

Man Date: Dec.2024 **Expiry Date**: Nov.2026

Each unit dose contains: Vitamin E (d-Alpha Tocopheryl acetate): 268 mg AT / 400 IU

Non-Medicinal Ingredient: Gelatin, Glycerin, Soybean oil.

Test	Method	Specifications	Result
Description	In-House	Clear Oval Soft Gel Filled with Yellow Oily Liquid	Complies
Weight variation	USP <2091>	600.00mg ± 10%	604.15 mg
Disintegration time	USP	NMT 30 minutes	09 minutes
Microbial Test			
Total Plate count	USP<2021>	NMT 100,000 CFU/g	<10CFU/g
Yeast & Mold	USP<2021>	NMT 1000 CFU/g	<10CFU/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:** Feb.21, 2025	
This is to certify that Medicap Laboratories products are manufactured under strict GMP conditions.			