BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique Potassium (60ct)		
Product Code:	70-0161		
Product type:	Capsule		
Color/Size/Shape:	Clear-Clear size "0" veggie. capsule filled with white powder.		
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	80079594		
Storage Conditions:	Store in cool, dry temperature		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	Aug.03,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim**	**Tolerance limits**
Potassium	100.00 mg	Not Assayed. Product is manufactured quantification by input to contain 100.00 mg of Potassium
List of Non-Medicinal Ingredients		
Dicalcium phosphate, Hypromellose, Magnesium stearate,Microcrystalline cellulose, Silicon dioxide		

Manufacturing Date	Aug.03,2026	**Biowell Lot #**	BL082609
Expiry Date	JL-2029		

BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Clear-Clear size "0" veggie. capsule filled with white powder**	Clear-Clear size "0" veggie. capsule filled with white powder
Disintegration	**USP <2040>**	**NMT 45 min**	10 min
Target Net Content	**Scale**	**520.00 mg**	520.00 mg
Weight variation	**USP <2091>**	**625.00 mg ± 5% (593.75 – 656.25) mg**	(593.75 – 656.25) 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)**	272 ppm (Refer to raw materials COAs)
Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >			

BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Product Disposition	Released ☑	Conditional Release ☐	Rejected ☐
QA Signature:	[signature]	Date:	OCT. 13, 2026

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Biogenique Potassium

Batch/Lot No: 012508

Man Date: Jan.2025 **Expiry Date**: Dec.2027

Each unit dose contains: Potassium (Potassium Chloride): 100.00mg.

Non-Medicinal Ingredient: Hypromellose, Silicon Dioxide.

Test	Method	Specifications	Result
Description	In house	Clear- Clear size "0" vegi. Capsule filled with white color powder.	Complies
Weight variation	USP <2091>	625.00 mg± 7.5% (578.13mg to 671.88mg)	628.31 mg
Lock Length	In house	21.30 mm –21.90mm	Complies
Disintegration time	USP	NMT 30 minutes	05 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	<0.001µg/kg b.w./ day
Cadmium		<0.09 µg/kg b.w./ day	<0.001µg/kg b.w./ day
Lead		<0.14 µg/kg b.w./ day	0.003µg/kg b.w./ day
Mercury		<0.29 µg/kg b.w./ day	<0.001µg/kg b.w./ day
Quality Approved: *Foram Patel*		Date: Jan.31, 2025	
This is to certify that biowell Laboratories products are manufactured under strict GMP conditions.			

Medicap Laboratories

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Biogenique Potassium

Batch/Lot No: 240546

Man Date: May.2024 **Expiry Date**: Apr.2027

Each unit dose contains: Potassium (Potassium Chloride): 100.00mg.

Non-Medicinal Ingredient: Hypromellose, Silicon Dioxide.

Test	Method	Specifications	Result
Description	In-House	Clear-Clear size "0" vegi. Capsule filled with white color Powder.	Complies
Weight variation	USP <2091>	625.00 mg± 7.5% (578.13mg/cap to 671.88mg/cap)	629.34 mg
Lock Length	In house	21.30 mm –21.90mm	Complies
Disintegration time	USP	NMT 30 minutes	14 minutes
Microbial Test			
Total Plate count	USP<2021>	NMT 100,000 CFU/g	60 CFU/g
Yeast & Mold	USP<2021>	NMT 1000 CFU/g	20 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	0.010 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.