

BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	8-Aug-2024	8-Aug-2027	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0038 v.6.1	: Supersedes
QA/QC Approval:	Jaron Hughes	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

POTASSIUM BROMIDE

BIO ACTIVE GRADE / KBRO-2220-10

LOT#: KBRO-0124-00002

KBr Δ F.W. 119.00 g/mol Δ CAS#: 7758-02-3

Manufacturing Date: 11/07/23 Retest Date: 11/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 02/07/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or exceeds USP and EP Specifications

TEST	SPECIFICATION	TEST RESULT	
Acidity or Alkalinity	Passes Test	Passes Test	
Appearance of Solution	Clear and Colorless	Clear and Colorless	
Assay	98.5 – 100.5%	99.2%	
Bromates	Passes Test	Passes Test	
Heavy Metals	10 ppm max.	< 10 ppm	
Identification	A	Passes Test	
	B	Passes Test	
Iodides	Passes Test	Passes Test	
Limit of Chlorine	0.6% max.	<0.6%	
Limit of Iron	20 ppm max.	< 20 ppm	
Loss on Drying	1.0% max.	<1.0%	
Magnesium and Alkaline Earth-Metals	0.02% max.	<0.02%	
Sulfates	0.01% max.	<0.01%	
Trace Metals	Arsenic (As)	5 ppm max.	<0.45 ppm
	Copper (Cu)	5 ppm max.	<3.0 ppm
	Iron (Fe)	5 ppm max.	<3.0 ppm
	Lead (Pb)	5 ppm max.	<3.0 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0014

CAUTION STATEMENT: For manufacturing, processing, or repacking.

CAUTION STATEMENT: Rx only.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product, or Household Item.

STATEMENT: Meets the chemical testing specifications of the current edition of the European Pharmacopoeia.

OVI STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: Campbell Date: 8/19/24 Job Title: Senior Quality Manager

Reviewed by: Joan Highm Date: 8/19/24 Job Title: QA Supervisor