

BIOSPECTRA

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

Effective Date:	26-Mar-2021	26-Mar-2024	: Date of Next Review
Prepared By:	Jared L Lobb	16-001195 v.5.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

POTASSIUM BROMIDE

BIO ACTIVE GRADE / NEW CODE KBRO-2220-25

(HISTORICAL CODE PB2220-K025)

LOT#: KBRO-0123-00003

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

Manufacturing Date: 11/30/22 Retest Date: 11/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 2/5/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or exceeds USP Specifications

TEST	SPECIFICATION	TEST RESULT	
Acidity or Alkalinity	Passes Test	Passes Test	
Appearance of Solution	Clear and Colorless	Clear and Colorless	
Assay	98.0 – 100.5%	99.5%	
Bromates	Passes Test	Passes Test	
Heavy Metals	10 ppm max.	< 10 ppm	
Identification	A Passes Test	Passes Test	
	B Passes Test	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.	0.1%	
Magnesium and Alkaline Earth-Metals	0.02% max.	<0.02%	
Sulfates	0.01% max.	<0.01%	
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001310

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: Janm Singh Date: 2/16/23 Job Title: QA Specialist
Reviewed by: Cause Allert Date: 2/16/23 Job Title: Assoc. Director of Quality