DCN: BSI-COA-0285 v.1.0



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

Effective Date:	14-SEP-2023		14-SEP-2026	: Date of Next Review
Prepared By:	Amy Yencho		Not Applicable	: Supersedes
QA/QC Approval:	Carissa Albert		James Piper	: Management Approval
Reason for Revision:	See Revision History in MasterControl	l.		

## **CERTIFICATE OF ANALYSIS**

## POTASSIUM BROMIDE

## BIO ACTIVE GRADE / KBRO-2302-25

LOT#: KBRO-0123-00035

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

Manufacturing Date: 8/9/23 Retest Date: 8/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 9/9/23 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%	99.6%
Bromates		Passes Test	Passes Test
Heavy Metals		≤ 10 ppm	<10 ppm
Identification A		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Iodides		Passes Test	Passes Test
Limit of Chlorine		≤ 0.6%	<0.6%
Limit of Iron		≤ 20 ppm	<20 ppm
Loss on Drying		≤ 1.0%	0.2%
Magnesium and Alkaline Earth-Metals		$\leq 0.02\%$	<0.02%
Sulfates		$\leq 0.01\%$	<0.01%
Trace Metals	Arsenic (As)	≤ 5 ppm	<0.45 ppm
	Copper (Cu)	≤ 5 ppm	<3.0 ppm
	Iron (Fe)	≤ 5 ppm	<3.0 ppm
	Lead (Pb)	≤ 5 ppm	0.40 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0014

<u>CAUTION STATEMENT:</u> For manufacturing, processing, or repackaging.

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## 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.

RESIDUAL SOLVENTS 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: Aud Mc(all Date: 9/21/23 Job Title: QA Moter. Disp. Supervisor