

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	16-001935 v.4.0	: 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-0122-00090

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

Manufacturing Date: 10/9/22 Retest Date: 10/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 11/4/22 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%	98.3%
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.	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.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.
		< 5 ppm
		< 5 ppm
		< 5 ppm
		< 5 ppm

COUNTRY OF ORIGIN: U.S.A.TEST METHOD REFERENCE: DCN: 16-001310CAUTION STATEMENT: For manufacturing, processing, or repacking in the preparation of a new drug or new animal drug limited by Federal law to investigational use.

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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.

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: James Hugh Date: 11/10/22 Job Title: QA Specialist
Assoc. Director

Reviewed by: Cassie Allert Date: 11/10/22 Job Title: of Quality