BI●SPECTRA

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

Effective Date:	16-Jan-2020		16-Jan-2023	: Date of Next Review
Prepared By:	Kyle Snyder		16-001195 v.3.0	: Supersedes
QA/QC Approval:	Carissa McCollian		Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.			

CERTIFICATE OF ANALYSIS
POTASSIUM BROMIDE
BIO ACTIVE GRADE / PB2220-SAMPLE COA
LOT#: PB2220-006-0120

KBr ⁁ F.W. 119.00 ⁁ CAS#: 7758-02-3
Manufacturing Date: 10/21/2019   Retest Date: 10/31/2021
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
Packaging Date: Sample CoA   Packaging Site: Sample CoA
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%	99.7%
Bromates		Passes Test	Passes Test
Heavy Metals		10 ppm max.	< 10 ppm
Identity	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.

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Active Pharmaceutical Ingredient for use in Drug Product Manufacturing. 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.

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: _____ Date: _1/21/20_ Job Title: _QA Supervisor_

Reviewed by: _____ Date: _1/21/20_ Job Title: _QA Manager_