BIOSPECTRA

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

Effective Date:	25-Jun-2020	25-Jun-2023	: Date of Next Review
Prepared By:	Amy Hosein	Not Applicable	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

POTASSIUM BROMIDE

BIO ACTIVE GRADE / PB2220-G500

LOT#: PB2220-008-0620

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

Manufacturing Date: 6/12/20 Retest Date: 6/30/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 6/13/20 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 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 use in development only not for commercial distribution.

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: _____ Date: 6/29/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 6/29/20 Job Title: QC Manager