BIOSPECTRA

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

Effective Date:	26-Feb-2018	26-Feb-2021	: Date of Next Review
Prepared By:	Danielle Gathagan	Not Applicable	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

POTASSIUM BROMIDE

CERTIFICATE OF ANALYSIS

BIO ACTIVE GRADE / PB2220 – G500

LOT#: PB2220-002-0219

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

Manufacturing Date: 1/27/2019 Retest Date: 1/31/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 3/3/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or exceeds USP Specifications

TEST		SPECIFICATION	TEST RESULT
Acidity or Alkalinity		To Pass Test	Passes Test
Appearance of Solution		Clear and Colorless	Clear and Colorless
Assay		98.0 – 100.5%	99.01%
Bromates		To Pass Test	Passes Test
Heavy Metals		10 ppm max.	< 10 ppm
Identity	A	To Pass Test	Passes Test
	B	To Pass Test	Passes Test
Iodides		To Pass Test	Passes Test
Limit of Chlorine		0.6% max.	<0.01%
Limit of Iron		20 ppm max.	< 20 ppm
Loss on Drying		1.0% max.	0.1125%
Magnesium and Alkaline Earth-Metals		0.02% max.	<0.02%
Sulfates		0.01% max.	<0.01%
Trace Metals	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm
	Arsenic (As)	5 ppm max.	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001310

CAUTION STATEMENT: For use in development only and not for commercial distribution.

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.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared By: _____ Date: 3/4/19

Reviewed By: _____ Date: 3/4/19