# BIOSPECTRA

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

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|---|---|---|---|
| Effective Date: | 14-Apr-2020 | 14-Apr-2023 | : Date of Next Review |
| Prepared By: | Amy Hosein | 16-001195 v.4.0 | : Supersedes |
| QA/QC Approval: | Wendy Santay | Dora Meissner | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

# CERTIFICATE OF ANALYSIS

## POTASSIUM BROMIDE

## BIO ACTIVE GRADE / PB2220-K025

## 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 manufacturing, processing, or repacking.

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: 6/25/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 06/25/20 Job Title: QA Manager