

# BIOSPECTRA

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

|                      |                                       |                    |                       |
|----------------------|---------------------------------------|--------------------|-----------------------|
| Effective Date:      | 8-Aug-2024                            | 8-Aug-2027         | : Date of Next Review |
| Prepared By:         | Carissa Albert                        | BSI-COA-0038 v.6.1 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                          | Wayne Talamonti    | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl |                    |                       |

## CERTIFICATE OF ANALYSIS

### POTASSIUM BROMIDE

### BIO ACTIVE GRADE / KBRO-2220-25

### LOT#: KBRO-E05-0526-0021

KBr  $\Delta$  F.W. 119.00 g/mol  $\Delta$  CAS#: 7758-02-3

Manufacturing Date: 5/3/26 Retest Date: 5/31/28

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 5/4/26 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or exceeds USP and EP Specifications

| TEST                                | SPECIFICATION       | TEST RESULT         |           |
|-------------------------------------|---------------------|---------------------|-----------|
| Acidity or Alkalinity               | Passes Test         | Passes Test         |           |
| Appearance of Solution              | Clear and Colorless | Clear and Colorless |           |
| Assay                               | 98.5 – 100.5%       | 99.3%               |           |
| 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.          | <0.45 ppm |
|                                     | Copper (Cu)         | 5 ppm max.          | <3.0 ppm  |
|                                     | Iron (Fe)           | 5 ppm max.          | <3.0 ppm  |
|                                     | Lead (Pb)           | 5 ppm max.          | <0.15 ppm |

COUNTRY OF ORIGIN: U.S.A.TEST METHOD REFERENCE: DCN: BSI-ATM-0014

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: 5/28/20 Job Title: QA Tech II

Reviewed by:  Date: 5/28/20 Job Title: QA Tech III