

POTASSIUM BROMIDE, API, USP Grade (Blend Batch)

INTENDED FOR USE AS AN ACTIVE PHARMACEUTICAL INGREDIENT

Potassium Bromide – Blend Batch, is the product code for the blend of multiple production batches to provide the end-user with a larger blended, uniform Lot size. Potassium Bromide is used as an active substance in veterinary medicine as an anti-seizure medication.

KBr

CAS #: 7758-02-3

Molecular Formula: KBr

Solubility in Water (g/L): 119

F.W.: 119.00 g/mol

Lead Time: 3-months

Minimum Order Quantity: 100kg

BIO ACTIVE GRADE | Product Code: KBRO-2302

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



These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

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



POTASSIUM BROMIDE API Grade

|  Key Compliance Attributes of BioSpectra Grades | Bio Active Grade ICH-Q7 Compliant Manufactured |
|--|---|
| Suitable for Research and Diagnostic | ✓ |
| Each Batch 100% Analyzed | ✓ |
| Management of Change | ✓ |
| Validated Analytical Methods | ✓ |
| Compendial Testing | ✓ |
| Trace Metals Analyzed | ✓ |
| Stability Testing Program | ✓ |
| BioSpectra Supply Chain Audit Trail | ✓ |
| Product Origin Statement | ✓ |
| Customer Quality Audits | ✓ |
| Validated Manufacturing Process | ✓ |
| US Manufactured at BioSpectra | ✓ |
| Customized Additional Specifications | ✓ |
| Multi-Compendial Testing | ✓ |
| Low Bioburden Low Endotoxin (LBLE) | ✓ |
| Enzyme Tested | ✓ |
| Suitable for use as Excipient | ✓ |
| Microbial / Endotoxin Tested | ✓ |
| Manufactured in FDA Registered Facility | ✓ |
| Customized Manufacturing Schedule | ✓ |
| Custom Regulatory Packet | ✓ |
| Accelerated Stability | ✓ |
| Video Conference access to BioSpectra Sites | ✓ |
| Complete access to Product Traceability | ✓ |
| Access to Supply Chain Information | ✓ |
| ICH-Q7 Qualified Utilities | ✓ |
| ICH-Q7 Compliant Manufactured | ✓ |
| Type II Drug Master File | ✓ |
| Suitable for use as Active Ingredient | ✓ |

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Active Grade: Intended for use as ICH-Q7 Compliant Active Pharmaceutical Ingredient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.



General Product Description:

- The manufacturing of Potassium Bromide KBRO-2302 is performed at BioSpectra's Bangor, PA facility and utilizes multiuse equipment. Equipment used in the manufacturing of Potassium Bromide Bio Active grade is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- Potassium Bromide is a White Crystalline product.
- Molecular Formula: KBr
- Molecular Weight: 119.00 g/mol.
- CAS Number: 7758-02-3.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Potassium Bromide KBRO-2302 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Potassium Bromide manufactured at BioSpectra and any raw materials used in the manufacture of Potassium Bromide at BioSpectra are not subject to genetic modification.
- Synonymns: Bromide Salt of Potassium, Kalii bromidum.

GMP Compliance:

Bio Active Grade Potassium Bromide KBRO-2302 is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Potassium Bromide is not suitable to be used as a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for Potassium Bromide is two years from the date of manufacture.

Storage and Shipping Conditions:

- Ship and Store between 15°C and 30°C.
- Store in a clean and dry area.
- Store in the original container.

Package Sizes:

10kg, 25kg and 50kg pails.