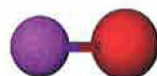




POTASSIUM BROMIDE



BIO ACTIVE GRADE REGULATORY PACKET

Signature/Date:

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1. POTASSIUM BROMIDE BIO ACTIVE GRADE

1.1. General Product Information

- 1.1.1. Product Name:
 - 1.1.1.1. Potassium Bromide
- 1.1.2. Product Code:
 - 1.1.2.1. Current Code: KBRO-2201, KBRO-2220, KBRO-2221, KBRO-2301
 - 1.1.2.2. Historic Code: PB2201, PB2220, PB2221, PB2301
- 1.1.3. Scope:
 - 1.1.3.1. This regulatory packet will provide the quality and regulatory information regarding the manufacturing, testing, packaging, storage, release, shipping, and handling of Bio Active Grade Potassium Bromide manufactured by and at the BioSpectra, Bangor, PA facility.
- 1.1.4. Molecular Formula:
 - 1.1.4.1. KBr
- 1.1.5. Molecular Weight:
 - 1.1.5.1. 119.00 g/mol.

1.2. Manufacturing, Packaging, Release Site and Supplier Information

- 1.2.1. General Information:
 - 1.2.1.1. BioSpectra manufactures Potassium Bromide in its Bangor, PA facility. Potassium Bromide is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
- 1.2.2. Manufacturing:
 - 1.2.2.1. The Manufacturing of Potassium Bromide is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Potassium Bromide is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
- 1.2.3. Packaging:
 - 1.2.3.1. The packaging of Potassium Bromide occurs in the following BioSpectra site: BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
- 1.2.4. Testing for Release:
 - 1.2.4.1. Testing and release of Potassium Bromide is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
- 1.2.5. GMP Compliance Statement:
 - 1.2.5.1. Bio Active Grade Potassium Bromide 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

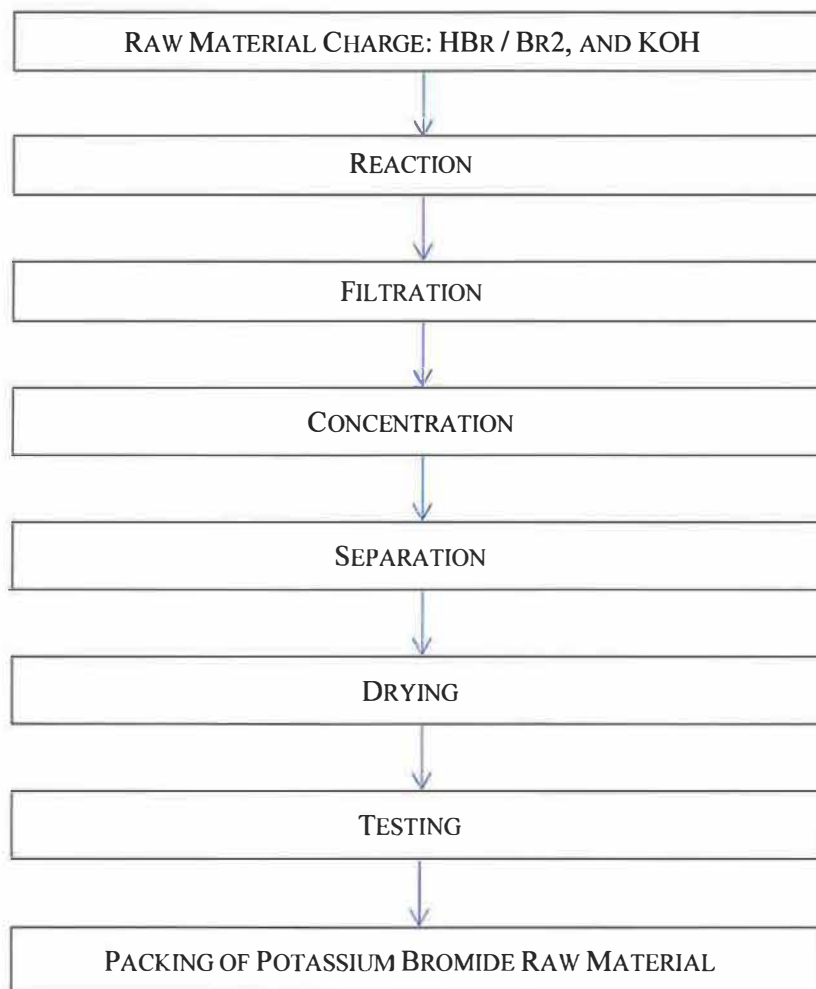
1.3. Physico-chemical Information

- 1.3.1. CAS Number:
 - 1.3.1.1. 7758-02-3



- 1.3.2. Origin:
- 1.3.2.1. The origin of Potassium Bromide is through chemical manufacturing using approved raw materials, which are further purified in accordance with ICH Q7 guidelines. Only raw materials of mineral and inorganic origin are used in the synthesis and purification of Potassium Bromide.
- 1.3.3. Synonyms:
- 1.3.3.1. Bromide Salt of Potassium
- 1.3.3.2. Hydrobromic Acid Potassium Salt
- 1.3.4. Morphological Form:
- 1.3.4.1. White Crystalline Powder
- 1.3.5. Manufacturing Process:
- 1.3.5.1. The manufacturing process for Potassium Bromide is performed by the following:

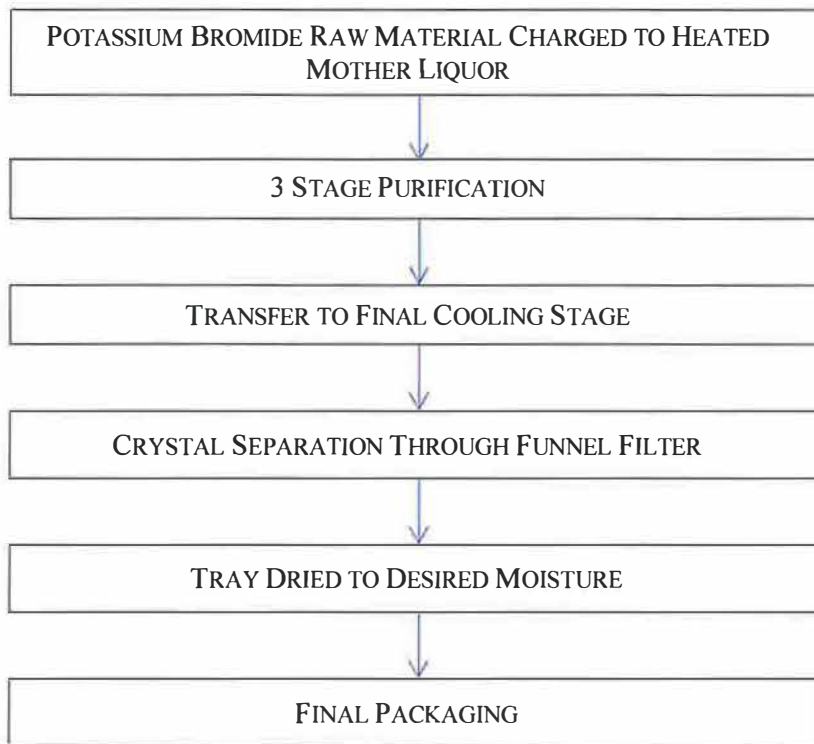
Approved Supplier Raw Material Synthesis



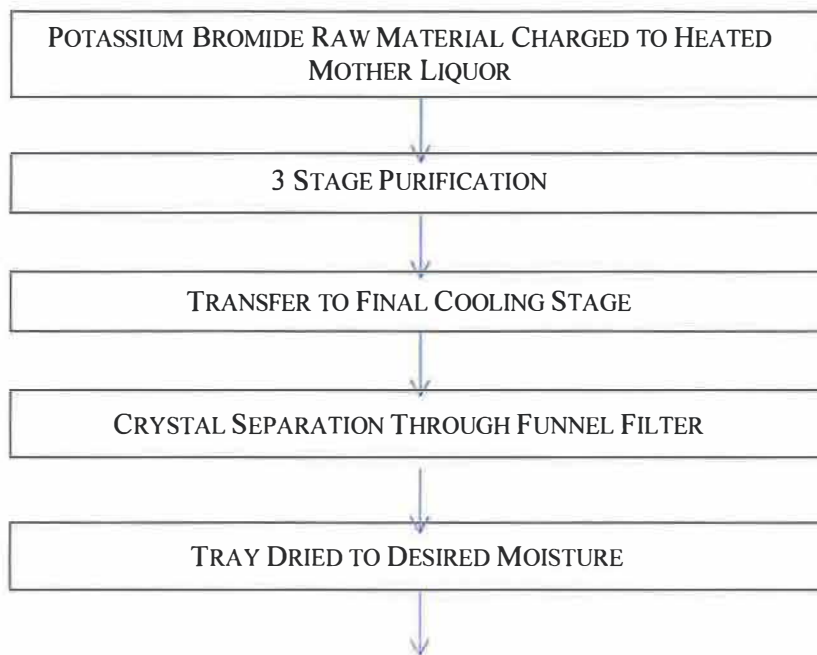
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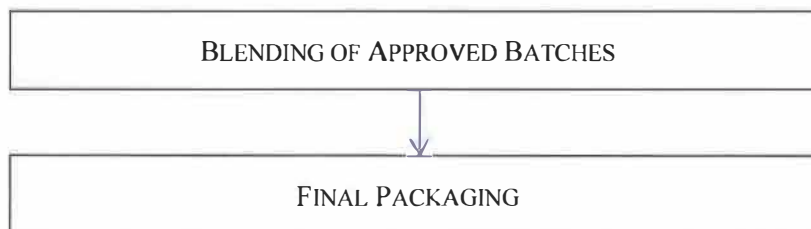
BioSpectra Active Pharmaceutical Ingredient Manufacturing Process



BioSpectra Active Pharmaceutical Ingredient Manufacturing Process (Blend)



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1.3.6. Specifications:

1.3.6.1. Available upon request.

1.4. Regulatory Information

1.4.1. Compendial Compliance:

1.4.1.1. USP Monograph

1.4.2. Master File:

1.4.2.1. Veterinary Master File (VMF) is available for this product.

1.4.2.2. EDQM Certificate of Suitability is currently not available for this product.

1.4.3. REACH:

1.4.3.1. Refer to the Potassium Bromide Safety Data Sheet for the REACH Number or contact your Commercial Team Representative for further information.

1.4.4. BSE/TSE Statement:

1.4.4.1. Potassium Bromide is of mineral and inorganic origin and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that BSE/TSE is not a concern based on this evaluation. Potassium Bromide, Bio Active Grade and its raw materials are not of animal origin.

1.4.5. Allergens Statement:

1.4.5.1. Potassium Bromide manufactured by BioSpectra and its raw materials are not manufactured with or using any of the following allergenic substances: Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanuts and products thereof, Soybeans and products thereof, Milk and products thereof (including lactose), Celery and products thereof, Mustard and products thereof, Sesame seeds and products thereof, Lupin and products thereof, Molluscs and products thereof, Sulphur dioxide and sulphites at >10 mg/kg as SO₂, Nuts, i.e., Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), Pistachio nuts (*Pistacia vera*), Macadamia or Queensland nuts (*Macadamia ternifolia*) and products thereof, Beef, Chicken, Pork, Azo Dyes, Benzoic Acid, Tartrazine, Vanillin, Cocoa, Cinnamon, Coriander, Yeast, Glutamate, Legumes, and Corn. BioSpectra has evaluated the Raw Material Supply through the Supplier Qualification Program.



- 1.4.6. Genetically Modified Organisms (GMO) Statement:
- 1.4.6.1. Potassium Bromide is of mineral and inorganic origin and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that genetic modification is not a concern based on this evaluation.
- 1.4.7. Residual Solvents Statement:
- 1.4.7.1. BioSpectra can state based on the manufacturing process and the controlled handling and storage of this product that the Potassium Bromide manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. There are no Class 1, 2, 3, or other solvents used in the manufacture of Potassium Bromide, Bio Active Grade or its raw materials. BioSpectra does not specifically analyze Potassium Bromide, Bio Active Grade, or its raw materials, for residual solvents.
- 1.4.8. Metal Catalyst and Metal Reagent Residues Statement:
- 1.4.8.1. BioSpectra can state that metal catalysts and metal reagents are not intentionally added or introduced to the BioSpectra manufacturing process for Potassium Bromide, Bio Active Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that catalysts are not used in the raw material manufacturing process based on this evaluation.
- 1.4.9. Pallet Statement:
- 1.4.9.1. BioSpectra can state that all wooden pallets used in the packaging and shipping of Potassium Bromide manufactured at BioSpectra are ISPM 15 compliant.
- 1.4.10. Elemental Impurities Statement:
- 1.4.10.1. BioSpectra's Potassium Bromide, Bio Active Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.
- 1.4.11. Melamine Statement:
- 1.4.11.1. Potassium Bromide, Bio Active Grade has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that melamine is not a risk based on this evaluation. BioSpectra additionally analyzes Potassium Bromide annually for Melamine; specification 2.5 mg/kg max.
- 1.5. Miscellaneous Product Information**
- 1.5.1. Description of Batch:
- 1.5.1.1. The Potassium Bromide process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan. Individual batch yield is additionally determined for each manufactured batch and documented in the respective batch record.
- 1.5.2. Lot/batch numbering system:
- 1.5.2.1. The lot numbering system at BioSpectra employs the following format: 4 alphanumeric digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as: KBRO-0123-00001.



- 1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where KBRO represents Potassium Bromide. The fifth and sixth digits are numeric digits which indicate the site of final packaging, where 01 represents the Bangor, PA facility. The seventh and eighth digits are numeric digits which indicate the year the batch record was issued, where 23 represents 2023. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first Potassium Bromide batch of 2023 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first of the new calendar year.
- 1.5.3. Expiration date and/or recommended re-evaluation interval:
- 1.5.3.1. The current recommended retest date for Potassium Bromide, Bio Active Grade is available in the BioSpectra Product Retest and Expiration Date List, DCN: BSI-LST-0239, and is based on current available stability data in accordance with BioSpectra's Stability Testing Program. Additionally, the recommended retest or expiration date will be available on the Product Specific Certificate of Analysis, as applicable.
- 1.5.4. Storage and shipping conditions:
- 1.5.4.1. Store in a tightly closed container. Store between 15-30°C (59-86°F), in a dry, well-ventilated area away from incompatible substances. Hygroscopic.
- 1.5.5. Packaging
- 1.5.5.1. Packaging information is available through the following:
<https://BioSpectra.us/packaging>
- 1.6. Contact Information:**
- 1.6.1. <https://www.biospectra.us/about-us/commercial-marketing-team>