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# DEGRADATION AND IMPURITY PROFILE REPORT: POTASSIUM BROMIDE

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## 1. PURPOSE AND SCOPE:

- 1.1. The impurity profiling of Potassium Bromide was intended to identify and possibly quantify impurities found in the Potassium Bromide product manufactured at BioSpectra, in the Bangor, PA facility.
  - 1.1.1. In the case where an impurity was found, a limit was set to the maximum allowable present without measurable compromise to predetermined critical quality attributes or toxicity. In the case where a limit could not be set, a procedure was written and followed, to identify if the possible impurity is present or not (i.e. an identity test, which is qualitative and not quantitative.)
  - 1.1.2. The profiling results and data will allow BioSpectra to further understand the purity and characteristics of Potassium Bromide.
  - 1.1.3. The four stages of Potassium Bromide that were tested are Raw Material, Mother Liquor, Wet Crystals and Finished Goods.
  - 1.1.4. The tests that were used to determine the presence of impurities and degradation products were as follows:
    - 1.1.4.1. Appearance of Solution
      - 1.1.4.1.1. RM (each lot) and FG Beginning Drum Batch 1.
    - 1.1.4.2. Assay
      - 1.1.4.2.1. RM (each lot), ML, WC Batch 1, FG Beginning Drum Batch 1.
    - 1.1.4.3. Bromates
      - 1.1.4.3.1. RM (each lot) and FG Beginning Drum Batch 1.
    - 1.1.4.4. Elemental Impurities with Addition of Iron
      - 1.1.4.4.1. RM (each lot), ML, WC Batch 1, FG Beginning Drum Batch 1.
    - 1.1.4.5. Identification A (Bromide)
      - 1.1.4.5.1. RM (each lot) and FG Beginning Drum Batch 1.
    - 1.1.4.6. Identification B (Potassium)
      - 1.1.4.6.1. RM (each lot) and FG Beginning Drum Batch 1.
    - 1.1.4.7. Limit of Chlorine
      - 1.1.4.7.1. RM (each lot), ML, WC Batch 1, FG Beginning Drum Batch 1.
    - 1.1.4.8. Loss on Drying
      - 1.1.4.8.1. RM (each lot) and FG Beginning Drum Batch 1.
- 1.2. All results were recorded in the appropriate laboratory documentation. The results are detailed in section 4 of this report. This report includes all relevant data as well as references to the initial documented results. The report discusses any impurities found in the product and includes a specification for any limits on the impurities found, when applicable.

## 2. RESPONSIBILITIES:

- 2.1. The Executive Director of Quality Control was responsible for control, training, implementation and maintenance of the protocol.
- 2.2. The QC Analysts were responsible for performing the testing stated in the protocol and recording all results in the Validation notebook.
- 2.3. The QC Systems team, or qualified designee, is responsible for completing the Degradation and Impurity Testing Report.

## 3. REFERENCES:

- 3.1. BSI-ATM-0014, Potassium Bromide Testing Methods
- 3.2. BSI-ATM-0080, Analytical Method of Analysis: Potassium Bromide via ICP-MS
- 3.3. BSI-SOP-0102, Degradation and Impurity Profiling SOP
- 3.4. BSI-SOP-0303, NexION 350X ICP-MS SOP

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**4. PROCEDURE:****4.1. APPEARANCE OF SOLUTION**

4.1.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Appearance of Solution testing are detailed in the table below.

**TABLE 1: APPEARANCE OF SOLUTION**

| Lot Number                   | Stage of Material | Specification       | Result              |
|------------------------------|-------------------|---------------------|---------------------|
| RMAT-1221-0044               | Raw Material      | Monitor             | Clear and Colorless |
| KBRO-0122-00024-PV Beginning | Finished Good     | Clear and Colorless | Clear and Colorless |

**4.2. ASSAY**

4.2.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Assay testing are detailed in the table below.

**TABLE 2: ASSAY**

| Lot Number                   | Stage of Material | Specification | Result |
|------------------------------|-------------------|---------------|--------|
| RMAT-1221-0044               | Raw Material      | 95.0% min     | 98.7%  |
| PMAT-0122-00079              | Mother Liquor     | Monitor       | 39.11% |
| KBRO-0122-00024-PV WC Top    | Wet Crystal       | Monitor       | 98.31% |
| KBRO-0122-00024-PV WC Bottom | Wet Crystal       | Monitor       | 95.95% |
| KBRO-0122-00024-PV Beginning | Finished Good     | 98.0-100.5%   | 98.2%  |

**4.3. BROMATES**

4.3.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Bromates testing are detailed in the table below.

**TABLE 3: BROMATES**

| Lot Number                   | Stage of Material | Specification | Result      |
|------------------------------|-------------------|---------------|-------------|
| RMAT-1221-0044               | Raw Material      | Monitor       | Passes Test |
| KBRO-0122-00024-PV Beginning | Finished Good     | Passes Test   | Passes Test |

**4.4. ELEMENTAL IMPURITIES**

- 4.4.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Elemental Impurity testing are detailed in the table below.

**TABLE 4: ELEMENTAL IMPURITIES**

| Lot Number                   | Stage of Material | Specification                       | Result   |
|------------------------------|-------------------|-------------------------------------|--|
| RMAT-1221-0044               | Raw Material      | Report                              | Refer to BSI-RPT-1050 for Elemental Impurity Results |
| PMAT-0122-00079              | Mother Liquor     |                                     |  |
| KBRO-0122-00024-PV WC Top    | Wet Crystal       |                                     |  |
| KBRO-0122-00024-PV WC Bottom | Wet Crystal       |                                     |  |
| KBRO-0122-00024-PV Beginning | Finished Good     | Report for As, Cu<br>Fe, Pb: ≤5 ppm |  |

**4.5. IDENTIFICATION A**

- 4.5.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Identification A testing are detailed in the table below.

**TABLE 5: IDENTIFICATION A**

| Lot Number                   | Stage of Material | Specification | Result      |
|------------------------------|-------------------|---------------|-------------|
| RMAT-1221-0044               | Raw Material      | Passes Test   | Passes Test |
| KBRO-0122-00024-PV Beginning | Finished Good     | Passes Test   | Passes Test |

**4.6. IDENTIFICATION B**

- 4.6.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Identification B testing are detailed in the table below.

**TABLE 6: IDENTIFICATION B**

| Lot Number                   | Stage of Material | Specification | Result      |
|------------------------------|-------------------|---------------|-------------|
| RMAT-1221-0044               | Raw Material      | Passes Test   | Passes Test |
| KBRO-0122-00024-PV Beginning | Finished Good     | Passes Test   | Passes Test |

**4.7. LIMIT OF CHLORINE**

- 4.7.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Limit of Chloride testing are detailed in the table below.

**TABLE 7: LIMIT OF CHLORINE**

| Lot Number                   | Stage of Material | Specification | Result |
|------------------------------|-------------------|---------------|--------|
| RMAT-1221-0044               | Raw Material      | 1.20% max     | 0.01%  |
| PMAT-0122-00079              | Mother Liquor     | Monitor       | 0.05%  |
| KBRO-0122-00024-PV WC Top    | Wet Crystal       | Monitor       | <0.01% |
| KBRO-0122-00024-PV WC Bottom | Wet Crystal       | Monitor       | 0.01%  |
| KBRO-0122-00024-PV Beginning | Finished Good     | 0.6% max      | <0.6%  |

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#### 4.8. **LOSS ON DRYING**

- 4.8.1. Refer to the Degradation and Impurity Profile Protocol: Potassium Bromide for testing methods and requirements. The results of the Loss on Drying testing are detailed in the table below.

**TABLE 8: LOSS ON DRYING**

| <b>Lot Number</b>            | <b>Stage of Material</b> | <b>Specification</b> | <b>Result</b> |
|------------------------------|--------------------------|----------------------|---------------|
| RMAT-1221-0044               | Raw Material             | Monitor              | 0.1122%       |
| KBRO-0122-00024-PV Beginning | Finished Good            | 1.0% max             | 0.1%          |

#### 5. **CONCLUSION:**

- 5.1. All samples met the specifications for the required analyses as dictated in the Degradation and Impurity Profile Protocol: Potassium Bromide.
- 5.2. It can be concluded that there are no additional identifiable impurities present in the Potassium Bromide material at any stage of the process at this time.