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POTASSIUM BROMIDE TESTING METHODS

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1. PURPOSE:

1.1. To provide the Quality Control (QC) Laboratory personnel with a procedure for testing the properties of Potassium Bromide, In-Process Mother Liquor (ML), Raw Materials (RM) and Finished Goods (FG).

2. SCOPE:

2.1. Applies to the testing of RM and all FG types in the Bangor, PA QC Laboratory. Methods include testing for all types of Potassium Bromide sold by BioSpectra.

3. RESPONSIBILITIES:

3.1. All QC Laboratory personnel are responsible for complying with this procedure.
3.2. The QC Manager is responsible for the implementation, control, training and maintenance of this procedure.

4. REFERENCES:

4.1. Balance SOP
4.2. Current USP
4.3. Laboratory Notebooks
4.4. Lambda 25 UV/Vis Operation and Calibration
4.5. NexION 350X ICP-MS SOP
4.6. Potassium Bromide Analytical Procedure
4.7. Potassium Bromide ML In-process Analysis and Specifications
4.8. Potassium Bromide In-Process Specifications
4.9. Potassium Bromide SDS
4.10. Result Reporting
4.11. Ro-Tap SOP
4.12. Standardization of Titrants
4.13. MF-50 Moisture Balance Operation and Calibration
4.14. XL200 pH/mV/Conductivity Meter SOP
4.15. VWR Gravity Convection Oven Operation and Calibration

5. EQUIPMENT:

5.1. Analytical Balance
5.2. Lambda 25 UV/Vis Spectrophotometer
5.3. MF-50 Moisture Balance
5.4. VWR Gravity Oven, or equivalent
5.5. XL200 pH/mV/Conductivity Meter
5.6. Ro-Tap
5.7. NexION 350X ICP-MS

6. ANALYTICAL PROCEDURES:

6.1. **MOTHER LIQUOR ASSAY** **Monitor:**

6.1.1. Standardize 0.1N $AgNO_3$ and 0.1N Ammonium Thiocyanate as per Standardization of Titrants.
6.1.2. Prepare a Nitric acid solution by diluting 14mL of nitric acid to 100mL with purified water.

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6.1.3. On the day of use, prepare *Ferric Ammonium Sulfate Indicator* by weighing 10g of Ferric Ammonium Sulfate. Transfer to a 100mL volumetric flask and dilute to volume with purified water.
6.1.4. Dissolve 2g of sample and dilute to 100mL with purified water.
6.1.5. To 10mL of the sample solution add the following:
6.1.5.1. 50mL of purified water
6.1.5.2. 5mL of the nitric acid solution
6.1.5.3. 25.00mL of 0.1N Silver Nitrate VS via burette
6.1.5.4. 2mL of Dibutyl phthalate
6.1.5.5. 2mL of *Ferric Ammonium Sulfate Indicator*
6.1.6. Mix and back titrate via burette the excess silver nitrate from the sample solution with Ammonium Thiocyanate that has previously been standardized in accordance with Standardization of Titrants to a light brown endpoint.
6.1.7. Run a blank determination.
6.1.8. The Limit of Chlorine test result will provide the "b" portion of the equation.

$$\% \text{ Br and Cl\%} = \left(\frac{(\text{mL of Blank} - \text{mL of } NH_4SCN) \times \text{N of } NH_4SCN \times 11.90}{(\textit{Sample Weight (g)} / 10)}\right) = \mathbf{a}$$

$$\%KBr = \mathbf{a} - 3.357\mathbf{b}$$

6.2. **MOTHER LIQUOR ABSORBANCE 2.000 a.u. max@ 260, 280 and 400nm:**
6.2.1. Dissolve 5ml of sample in 5ml of purified water. Swirl to dissolve completely. Refer to Lambda 25 UV/Vis Operation and Calibration to determine the absorbance of the sample; attach the printout to the appropriate summary sheet. If any absorbance is performed by properly trained Production personnel, then the result are to be recorded in the Bangor production absorbance results log book.
6.2.2.
6.2.2.1. If the any of the sample results are out of specification or if the sample result at 280nm exceeds the action limit of 0.27 a.u, notify the Director of Quality Control, QA, and Production Managers immediately

6.3. **WET CRYSTAL ABSORBANCE (1M) TOP/BOTTOM0.06 a.u. max@ 260nm, TOP/BOTTOM 0.05 a.u. max@ 280nm:**
6.3.1. Accurately weigh 2.98g of sample.
6.3.2. Transfer accurately weighed sample to a 50mL graduated cylinder and dilute to 25mL with purified water.
6.3.3. Swirl to dissolve completely.
6.3.4. Refer to Lambda 25 UV/Vis Operation and Calibration to determine the absorbance of the sample; attach the printout to the appropriate summary sheet.
6.3.5. If any absorbance is performed by properly trained Production personnel, then the result are to be recorded in the Bangor production absorbance results log book.

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6.4. **WET CRYSTAL MOISTURE 2% MAX AT TOP, 4% MAX AT BOTTOM:**

6.4.1. Refer to MF-50 Moisture Balance Operating and Calibration to determine the moisture of the sample.

6.4.2. Documentation of analysis should be recorded in the In-Process Moisture Analysis Log Book.

6.4.3. Notify the Director of Quality Control if the moisture result is not within specification. An out of specification moisture result could result in a particle size failure on finished goods.

FINISHED GOOD ANALYSIS

Particle Size Analysis should be the first analysis completed on the Finished Good Samples. Notify the Director of Quality Control of an out of specification result.

6.5. **ABSORBANCE (1M) Monitor @ 260 and 280nm:**

6.5.1. Accurately weigh 2.98g of sample.

6.5.2. Transfer accurately weighed sample to a 50mL graduated cylinder and dilute to 25mL with purified water.

6.5.3. Swirl to dissolve completely.

6.5.4. Refer to Lambda 25 UV/Vis Operation and Calibration to determine the absorbance of the sample; attach the printout to the appropriate summary sheet.

6.6. **ACIDITY OR ALKALINITY USP Passes Test:**

6.6.1. Weigh 10.0g of sample and dilute to 100mL with purified water (solution from Appearance of Solution can be used).

6.6.2. To 10mL of sample solution add 0.1mL of bromothymol blue TS.

6.6.3. If the solution is yellow, add 0.5mL of 0.01N NaOH. The solution must change to a blue hue in order to pass.

6.6.4. If the solution is blue, add 0.5mL of 0.01N HCl. The solution must change to a yellow hue in order to pass.

6.7. **APPEARANCE OF SOLUTION USP Clear and Colorless:**

6.7.1. Weigh 10.0g of sample and dilute to 100mL in a volumetric flask with purified water.

6.7.2. In an area with sufficient light, observe from all angles.

6.7.3. Solution should be clear and colorless when compared against a common background to a clear and colorless reference solution.

6.8. **ASSAY USP 98.0-100.5%:**

6.8.1. Standardize 0.1N $AgNO_3$ and 0.1N Ammonium Thiocyanate as per Standardization of Titrants.

6.8.2. Prepare a Nitric acid solution by diluting 14mL of nitric acid to 100mL with purified water.

6.8.3. On the day of use, prepare *Ferric Ammonium Sulfate Indicator* by weighing 10g of Ferric Ammonium Sulfate. Transfer to a 100mL volumetric flask and dilute to volume with purified water.

6.8.4. Dissolve 2.000g ±0.0005g of sample and dilute to 100mL with purified water.

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6.8.4.1. Sample must be dried for Finished Good samples and tested as-is for Raw Materials.

6.8.5. To 10mL of the sample solution add the following:
- 6.8.5.1. 50mL of purified water
- 6.8.5.2. 5mL of the nitric acid solution
- 6.8.5.3. 25.00mL of 0.1N Silver Nitrate VS via burette
- 6.8.5.4. 2mL of Dibutyl phthalate
- 6.8.5.5. 2mL of *Ferric Ammonium Sulfate Indicator*

6.8.6. Mix and back titrate via burette the excess silver nitrate from the sample solution with Ammonium Thiocyanate that has previously been standardized in accordance with Standardization of Titrants to a light brown endpoint.

6.8.7. Run a blank determination.

6.8.8. The Limit of Chlorine test result will provide the "b" portion of the equation.

$$\%\ Br\ and\ Cl\% = \frac{(mL\ of\ Blank - mL\ of\ NH_4SCN) \times N\ of\ NH_4SCN \times 11.90}{(Sample\ Weight\ (g) / 10)} = \mathbf{a}$$

$$\%KBr = \mathbf{a} - 3.357\mathbf{b}$$

6.9. **BROMATES** **USP Passes Test:**

6.9.1. To prepare Starch-mercuric iodide solution finely grind 1.0g of soluble starch with 5mL of purified water.

6.9.2. Pour the mixture into 100mL of boiling water containing 10mg of mercuric iodide.

6.9.3. Weigh 10.0g of sample and dilute to 100mL with purified water (solution from Appearance of Solution can be used).

6.9.4. To 10mL of sample solution add 1mL of the Starch-mercuric iodide solution.

6.9.5. Add 0.1mL of a 100g per L solution of potassium iodide.

6.9.6. Add 0.25mL of 0.5M sulfuric acid.

6.9.7. Allow to stand for five minutes away from light. There should be no blue or violet color present to pass.

6.10. **HEAVY METALS** **USP 10 ppm max.:**

6.10.1. *Standard Preparation:*

6.10.1.1. On the day of use, dilute 10.0mL of Lead Nitrate Stock solution with purified water to 100mL. Into a Nessler Color Comparison Tube, pipette 2mL of the standard lead solution and dilute to 25 mL. Adjust with 1N acetic acid or 6N ammonium hydroxide to a pH between 3.0 and 4.0, using a pH meter or short-range pH indicator paper as an external indicator, dilute to 40mL with purified water.

6.10.2. *Monitor Preparation:*

6.10.2.1. Weigh 2.00g of sample. Transfer to a Nessler Color Comparison Tube and dilute with purified water to 25 mL.

6.10.2.2. Add 2mL of the standard lead solution.

6.10.2.3. Adjust with 1N acetic acid or 6N ammonium hydroxide to a pH between 3.0 and 4.0, using a pH meter or short-range pH indicator paper as an external indicator, dilute to 40mL with purified water and mix.

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6.10.3. *Test Preparation:*

6.10.3.1. Weigh 2.00g of sample, transfer to a Nessler Color Comparison Tube and dilute with purified water to 25 mL

6.10.3.2. Adjust with 1N acetic acid or 6N ammonium hydroxide to a pH between 3.0 and 4.0, using a pH meter or short-range pH indicator paper as an external indicator, dilute to 40mL with purified water and mix.

6.10.4. *Procedure:*

6.10.4.1. To each of the tubes containing the Standard Preparation, the Test Preparation and the Monitor Preparation, add 2mL of pH 3.5 Acetate Buffer and 1.2mL of thioacetamide-glycerin base TS (mix 0.2mL of thioacetamide TS and 1mL of glycerin base TS, heat in a boiling purified water bath for approximately 20 seconds. Use immediately).

6.10.4.2. Dilute with purified water to 50mL, mix by inversion and allow to stand for 2 minutes.

6.10.4.3. View downward over a white surface: the color of the solution from the Test Preparation is not darker than the Standard Preparation and the color of the Monitor Preparation Solution is equal to or darker than that of the Standard Preparation in order to report as <10ppm.

6.11. **IDENTIFICATION TEST** **USP (A) Passes Test:**

6.11.1. **To prepare Chlorine TS** *(Chlorine Water)*—A saturated solution of chlorine in water. Place the solution in small, completely filled, light-resistant containers. Chlorine TS, even when kept from light and air, is apt to deteriorate. Store it in a cold, dark place. For full strength, prepare this solution fresh.

A. Weigh 4.5mg of sample and dissolve in 1mL of purified water.
Add chlorine TS dropwise
Dissolve by shaking with chloroform. The chloroform should turn from red-to-reddish brown.

B. Weigh 4.5mg of sample and dissolve in 1mL of purified water
Add 0.20mL of 0.1N silver nitrate and mix.
A yellowish-white precipitate will form.
Add 1mL of nitric acid. The precipitate is insoluble in nitric acid to pass test.
Add 1mL of 6N Ammonium Hydroxide. The precipitate should be slightly soluble.

6.12. **IDENTIFICATION TEST** **USP (B) Passes Test:**

6.12.1. Weigh 10.0g of sample and dilute to 100mL with purified water (solution from Appearance of Solution can be used).

6.12.2. To 1.0mL of sample solution add 0.20mL of freshly prepared Sodium Bitartrate TS.

6.12.2.1. Prepare Sodium Bitartrate TS by dissolving 1.00g of sodium bitartrate into 10mL of purified water.

6.12.3. Add 0.20mL of glacial acetic acid.

6.12.4. A precipitate is produced; utilize a glass rod to accelerate formation of precipitate.

6.12.5. Add 1mL of 6N Ammonium Hydroxide. The precipitate should be slightly soluble.

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6.13. **IODIDES** **USP Passes Test:**

6.13.1. Weigh 10.0g of sample and dilute to 100mL with purified water (solution from Appearance of Solution can be used).
6.13.2. To 5mL of sample solution add 0.15mL of a 10.5g per 100mL ferric chloride solution.
6.13.3. Add 2mL of dichloromethane.
6.13.4. Shake and allow solution to separate. The lower layer must remain colorless to pass.

6.14. **LIMIT OF CHLORINE** **USP 0.6% max:**

6.14.1. Standardize 0.1N $AgNO_3$ and 0.1N Ammonium Thiocyanate as per Standardization of Titrants.
6.14.2. Prepare a Nitric acid solution by diluting 14mL of nitric acid to 100mL with purified water.
6.14.3. Dissolve 1.000g ± 0.0005g of sample in 20mL of Nitric acid solution.
6.14.3.1. Sample must be dried for Finished Good samples and tested as-is for Raw Materials.
6.14.4. Add 5 mL of 30% Hydrogen Peroxide in the hood and the solution should turn yellow.
6.14.5. Prepare a blank determination by mixing 20mL of Nitric acid solution and 5mL of 30% Hydrogen Peroxide in a 50mL beaker.
6.14.6. Heat in a water bath until the solution becomes colorless.
6.14.7. Rinse the sides of the beaker with a small quantity of purified water and heat in the water bath for an additional 15 minutes.
6.14.8. Allow to cool and dilute with purified water to 50mL.
6.14.9. Add 5.00 mL of 0.1N Silver Nitrate VS via burette and 1 mL of Dibutyl phthalate.
6.14.10. Add 5 mL of *Ferric Ammonium Sulfate Indicator* and back titrate via burette the excess silver nitrate with 0.1N Ammonium Thiocyanate to a light brown endpoint.

$$\% Cl = \left(\frac{(\text{mL of Blank} - \text{mL of } NH_4SCN) \times N \text{ of } NH_4SCN \times 3.5453}{\textit{Sample Weight (g)}}\right) = \mathbf{b}$$

6.15. **LIMIT OF IRON** **USP 20ppm max:**

6.15.1. Prepare a 200mg per mL solution of citric acid.
6.15.2. *Iron Standard Solution*:
6.15.2.1. Weigh 0.863g of ferric ammonium and transfer to a 500mL volumetric flask.
6.15.2.2. Dissolve in 25mL of dilute sulfuric acid (prepared by diluting 5.5mL of concentrated sulfuric acid to 100mL with purified water).
6.15.2.3. Dilute to volume with purified water.
6.15.2.4. Transfer 1mL of ferric ammonium solution to a 10mL volumetric flask and Dilute to volume with purified water.
6.15.2.5. Transfer 2.5mL of the solution to a 50mL volumetric flask and dilute to volume with purified water. Prepare solution immediately for use.
6.15.3. *Test Solution:*
6.15.3.1. Weigh 10.00g of sample and dilute to 100mL with purified water (solution from Appearance of Solution can be used).
6.15.3.2. Transfer 5 ml of the solution prepared for the test for appearance of solution to a 10-ml volumetric flask, and dilute with water to volume.

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6.15.4. *Procedure*:
- 6.15.4.1. To 10mL of the iron standard solution and test solution, add 2.0 mL of the citric acid solution.
- 6.15.4.2. Add 0.1mL of thioglycolic acid.
- 6.15.4.3. Adjust the test and standard solutions to basic with ammonia water to litmus.
- 6.15.4.4. Dilute with purified water to 20mL. Let stand for 5 minutes, the test solution shall remain less pink than the standard solution.

6.16. **LOSS ON DRYING** **USP 1.0% max.:**
- 6.16.1. Dry an LOD vial in an oven at 105 ± 2˚C for 30 minutes. Cool for 15 minutes in a desiccator.
- 6.16.2. Place the LOD vial on the analytical balance and record the weight.
- 6.16.3. Tare the LOD vial and weigh 4 – 6 grams of sample and record results.
- 6.16.4. Place the LOD Vial containing the sample into the oven.
- 6.16.5. Dry the sample at 105 ± 2°C for 3 hours.
- 6.16.6. Allow to cool in the desiccator for 15 minutes prior to weighing.
- 6.16.7. Calculate Loss on Drying

$$\% \text{ LOD} = \text{initial } \frac{\text{sample weight (g)} - \text{final sample weight (g)}}{\text{initial sample weight (g)}} \times 100$$

6.17. **MAGNESIUM AND ALKALINE-EARTH METALS** **USP 0.02% max.:**
- 6.17.1. Prepare pH 10.0 ammonia-ammonium chloride buffer by dissolving 5.4g of ammonium chloride in 20mL of purified water and adding 20mL of ammonium hydroxide and diluting to 100mL with purified water.
- 6.17.2. To 200mL of purified water add the following:
  - 6.17.2.1. 0.1g of hydroxylamine hydrochloride
  - 6.17.2.2. 10mL of pH 10.0 ammonia-ammonium chloride
  - 6.17.2.3. 1mL of 0.1M zinc sulfate
  - 6.17.2.4. 0.2g of eriochrome black T trituration
  - 6.17.2.5. eriochrome black T trituration: Grind 200mg of eriochrome black T to a fine powder with 20g of potassium chloride.
- 6.17.3. Heat solution to about 40°C.
- 6.17.4. Titrate solution with 0.01M EDTA disodium titrant VS via burette until the violet color changes to deep blue.
- 6.17.5. Add 10.0g of sample dissolved in 100mL of purified water.
- 6.17.6. If no color change, report as no color change, <0.02%.
- 6.17.7. If the color changes to violet:
  - 6.17.7.1. Standardize 0.01M EDTA disodium titrant VS as per Standardization of Titrants
- 6.17.8. Titrate the solution with standardized 0.01M EDTA, not more than 5.0mL will be used or <0.02% Calculated as Ca.

6.18. **PARTICLE SIZE ANALYSIS** **#20 Mesh: 5% max.; #60 Mesh: 60% min.:**
- 6.18.1. ENSURE THAT EACH SIEVE IS INSPECTED AND CLEAN BEFORE USE. #20MESH SIEVE AND #60 SIEVE IS DEDICATED FOR KBr.

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6.18.2. Weigh 25-30g of sample into a sample bottle. Weigh and record the weight of the sample bottle including the cap.
6.18.3. Weigh each sieve individually and record the results.
6.18.4. Gently wipe the catch pan with a fine brush to remove any residual particles. Weigh and record the weight of the catch pan.
6.18.5. Arrange the sieves by increasing Sieve Number, so that the largest Sieve Number is on the bottom of the stack.
6.18.6. Connect the catch pan to the bottom sieve and place the stack in the groove of the Ro-Tap.
6.18.7. Pour the entire contents of the sample bottle into the top sieve being careful not to lose any crystals.
6.18.8. Place the cover on the sieves and tighten them into place with the two tension nuts.
6.18.9. Turn the power switch to "on."
6.18.10. Set the time to 5 minutes and press the "Fine" Button.
6.18.11. Press Start and the Ro-Tap will begin to intermittently shake.
6.18.12. When the timer expires, remove the Ro-Tap cover and reweigh each sieve and the empty sample bottle individually. Calculate the weight of the material retained on each sieve by subtracting the final weight from the initial weight.
6.18.13. In order to pass, no more than 5% may be retained on the #20 Sieve, at least 60% must be retained on the #60 Sieve, and at least 95% of the sample must be retained.

$$\%\ Retained = \frac{Weight\ of\ Material\ Retained\ (g)}{Weight\ of\ Material\ Sieved\ (g)} X100$$

6.19. **SULFATES** **USP 0.01% max:**

6.19.1. To prepare the sample weigh 2.0g of sample, transfer to a Nessler Color Comparison Tube and dilute to approximately 40mL with purified water and if necessary, neutralize the solution with hydrochloric acid to litmus.
6.19.2. Prepare standard by pipetting 0.2mL of 0.020N sulfuric acid into a Nessler Color Comparison Tube and dilute to approximately 40mL with purified water.
6.19.3. To both the sample and the standard add 1mL of 3N hydrochloric acid and 3mL of barium chloride TS.
6.19.4. Dilute the sample and standard solution to 50mL with purified water and allow to stand for 10 minutes. Any turbidity in the sample solution must not exceed that produced in the standard to pass.

6.20. **TRACE METALS** **COPPER, IRON, LEAD, ARSENIC 5PPM max:**

6.20.1. Follow the NexION 350X ICP-MS for sample preparation and analysis.

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