BIOSPECTRA
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To Whom It May Concern,

INTRODUCTION: The following analyses are conducted for Sodium Hydroxide 10N Solution, product code NH4150, in accordance with the Sodium Hydroxide 10N Testing Methods DCN: 19-002773 v.5.0 and Certificate of Analysis DCN: 19-002798 v.2.0. Specific details for the procedures were also obtained from NexION 350X ICP-MS SOP DCN: 16-001923 v.2.0.

1. APPEARANCE AND COLOR — Clear / Colorless Liquid:

1.1. Transfer 50mL of sample into a Nessler tube.
1.2. In order to pass, test solution is complete, clear, and colorless. Verify the solution appearance against a clear and colorless reference solution, such as purified water, and view against a color comparison plate with suitable lighting.

2. CHLORIDE — ≤5 ppm:

2.1. Thoroughly rinse Nessler tubes using purified water prior to use.
2.2. **Sample Preparation:**
  2.2.1. Weigh 2.0g of sample and quantitatively transfer to a 50mL Nessler Color Comparison Tube using purified water.
  2.2.2. Dilute to ~20mL with purified water.
  2.2.3. Slowly, using extreme caution, acidify the sample with nitric acid to litmus.
  2.2.4. Dilute to 50mL with purified water.
2.3. **5 ppm Standard Preparation:**
  2.3.1. Dilute 14.1µL of 0.02N HCl to ~40mL with purified water.
2.4. **Analysis:**
  2.4.1. To both the sample and standard solutions, add 1mL of concentrated nitric acid and 1mL of 0.1N Silver Nitrate TS.
  2.4.2. Mix and allow solutions to sit for 5 minutes using a calibrated timer.
  2.4.3. After 5 minutes, the turbidity in the sample solution does not exceed the turbidity produced by the standard when viewed against a dark background. Analyze turbidity utilizing the turbidity meter and record the sample NTU results.

3. ENDOTOXINS — ≤2.0 EU/mL:

3.1. Pipet 0.200mL of sample into a sterile vial and add 1.600 mL of LAL reagent water.
3.2. Add 0.160mL of concentrated Hydrochloric acid to acidify.
3.3. Check the pH of the solution with pH paper: solution must be acidic.
  3.3.1. If basic add HCl in increments until acidic.
    3.3.1.1. Add approximately 0.2mL of HCl.
3.4. Once acidic add sufficient buffer of a pH range ~9-10 until the solution is between pH 6-8.
  3.4.1. Add approximately 0.3mL of buffer.

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3.5. Dilute with LAL reagent water to a final volume of 10mL.
3.6. Follow the Endosafe Nexgen PTS Endotoxin Reader SOP for sample analysis.
3.6.1. The dilution factor is 50.

4. HEAVY METALS (as Pb) ≤1 ppm:

4.1. Refer to NexION 350X ICP-MS SOP for Instrument Set-Up and Use.
4.1.1. Sample Preparation:
4.1.2. General Notes:
4.1.2.1. Before use, all plasticware that is not rated as "metal-free", should first be rinsed with purified water, rinsed with 15% Nitric Acid, and then rinsed again with purified water. Plasticware rated as "metal-free" may be used as-is.
4.1.2.2. Glass should be avoided as it has high potential for metal and mineral contaminations.
4.1.2.3. Standard and sample solutions should be prepared in 50mL centrifuge tubes.
4.1.3. 1% Nitric Acid
4.1.3.1. Measure 14.5 mL of Trace Metal Grade Nitric Acid and transfer to a rinsed plastic 1000 mL volumetric flask. QS to 1000 mL with purified water.
4.1.4. 15% Nitric Acid
4.1.4.1. Dilute approximately 110 mL of Trace Metal Grade Nitric Acid to 500 mL with purified water.
4.1.4.2. The solution is only used to rinse glassware and plasticware.
4.1.5. **NaOH – Fe and Pb**
4.1.5.1. Sample Solutions
4.1.5.1.1. Weigh 0.10 g of sample on an analytical balance. Add 100 µL of Environmental Standard Mix 6 and QS to 50.0 g with 1% Nitric Acid.
4.1.5.2. Standard Curve Preparation:
4.1.5.2.1. 2 ppm Stock
4.1.5.2.1.1. Weigh 1.00 g of Instrument Calibration Standard 2 and QS to 50.0 g with 1% Nitric Acid
4.1.5.2.2. 100 ppb Stock
4.1.5.2.2.1. Weigh 2.50 g of 2 ppm Stock and QS to 50.0 g with 1% Nitric Acid.
4.1.5.2.3. Blank
4.1.5.2.3.1. Pipette 100 µL of Environmental Standard Mix 6 into the centrifuge tube. QS to 50.0 g with 1% Nitric Acid.
4.1.5.2.4. 1 ppb Standard
4.1.5.2.4.1. Pipette 0.50 mL of the 100 ppb Stock, add 100 µL of Environmental Standard Mix 6 and QS to 50.0 g with 1% Nitric Acid.
4.1.5.2.5. 4 ppb Standard
4.1.5.2.5.1. Pipette 2.00 mL of the 100 ppb Stock, add 100 µL of Environmental Standard Mix 6 and QS to 50.0 g with 1% Nitric Acid.

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4.1.5.2.6. 10 ppb Standard
4.1.5.2.6.1. Pipette 5.00 mL of the 100 ppb Stock, add 100 µL of Environmental Standard Mix 6 and QS to 50.0 g with 1% Nitric Acid.
4.1.5.2.7. 2 ppb Standard (used only as Continuing Check Verification sample (CCV))
4.1.5.2.7.1. Pipette 1.00 mL of the 100 ppb Stock, add 100 µL of Environmental Standard Mix 6 and QS to 50.0 g with 1% Nitric Acid.

5. IRON ≤2 ppm:

5.1. Refer to Heavy Metals (as Pb) for method of analysis.

6. NORMALITY 9.9N – 10.1N:

6.1. KHP (Potassium Hydrogen Phthalate) preparation:
6.1.1. Crush and dry a suitable amount of KHP at 120°C for 2 hours. Allow to cool to ambient temperature in a desiccator.
6.2. Burette preparation:
6.2.1. Fill a 25mL volumetric flask with sample. Quantitatively transfer the aliquot to a 250mL volumetric flask with purified water. Rinse the 25mL flask by filling the flask halfway with purified water, shaking it, then transferring the rinse to the 250mL volumetric flask. Perform the rinse procedure in duplicate. Fill the 250mL volumetric flask to volume with purified water. Mix well and cool to 25°±2°C. QS the sample solution to 250mL after cooling is complete.
6.2.2. Prime the 50mL burette by filling it with the diluted sample solution. Empty the burette and repeat.
6.2.3. Fill the burette to the required volume with the prepared sample solution.
6.3. Sample preparation:
6.3.1. Weigh 8.0000 – 8.2000g of the previously dried KHP into a 250mL beaker.
6.3.2. Add 100mL of purified water down the sides of the beaker to avoid the loss of KHP.
6.4. Analysis Procedure:
6.4.1. To the KHP solution, add phenolphthalein indicator.
6.4.2. Titrate the KHP using the sample solution in the burette, to a pink endpoint.
6.4.3. Calculate the normality using the following equation:

$$N = \frac{(KHP\ weight\ g)(KHP\ Purity)(10)}{(0.20423)(mL\ of\ NaOH\ sample\ solution)}$$

$$KHP\ Purity\ =\ Assay\ percent\ of\ KHP/100\ (from\ manufacturer's\ CoA)$$

$$0.20423\ =\ Formula\ weight\ of\ KHP/1000$$

$$10\ =\ Dilution\ Factor$$

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7. SODIUM CARBONATE ≤0.6%.:

7.1. **Preparation of 6N sulfuric acid Solution:**

7.1.1. To a 1L volumetric flask containing 600ml of cooled Purified Water, add slowly (using caution) 169mL of 96% sulfuric acid in small increments allowing to cool in between each addition. Dilute to the mark, mix thoroughly. Reagent may already be prepared.

7.1.2. Following the Standardization of Titrants SOP, perform a single check of the 6N sulfuric Acid normality concentration when the reagent is first prepared:

7.2. **Sample Analysis:**

7.2.1. Accurately weigh 48g of sample in an iodine flask then add 100mL of purified water. Stopper, swirl to mix, water seal the flask, and chill to room temperature in an ice bath.

7.2.2. While in an ice bath, slowly add the calculated volume of 6N sulfuric acid reagent required from the calculation below. Wash down the flask sides with purified water, swirl to mix, water-seal the flask, and then chill to room temperature.

$$\text{mL of 6N Sulfuric to add} = \frac{(\%\ Assay\ of\ sample)(sample\ weight)}{(4.00)(N\ of\ 6N\ Sulfuric)} - 5\text{mL}$$

7.2.3. Titrate with a standardized 1N H_2SO_4 and phenolphthalein TS using a 50mL buret to a precise clear endpoint (V1); add methyl orange indicator and continue the titration to the first pink endpoint (V2). Calculate the % Na_2CO_3 using the following equation:

$$\%\ Na_2CO_3 = \frac{(V_2 - V_1)\ x\ N\ of\ Titrant\ x\ 10.6}{sample\ weight\ (g)}$$

If there are any questions or concerns, please feel free to contact ra@biospectra.us.

Sincerely,

Cassie Baun

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