BIOSPECTRA
100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

To Whom It May Concern,

INTRODUCTION: The following analyses are conducted for Sodium Chloride 5M Solution, product code NC3150, in accordance with the Sodium Chloride 5M Testing Methods DCN: 19-003065 v.1.0 and Certificate of Analysis DCN: 19-003007 v.1.1. 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 Solution:

1.1. Transfer 50mL of the sample in a clean, dry color Nessler tube.
1.2. In order to pass, test solution is a clear, colorless solution. 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. ASSAY — 4.9-5.1M:

2.1. Standardize or perform a daily check of 0.1N $AgNO_3$ as per Standardization of Titrants.
2.2. Transfer 10mL of the sample solution into a 100mL volumetric flask and dilute to volume with purified water.
2.3. Accurately transfer 3mL of the diluted solution to a suitable titration vessel. Add 7mL of purified water, 10mL of glacial acetic acid, 75mL of methanol, and Eosin Y TS as the indicator.
2.4. While stirring, titrate with 0.1N Silver Nitrate TS to a pink endpoint. Each mL of 0.1N Silver Nitrate is equivalent to 5.844mg of Sodium Chloride.

$$M\ NaCl = \frac{(mL\ of\ titer)(N\ of\ titer)(10)}{3}$$

3. ENDOTOXIN — ≤2.5 EU/mL:

3.1. Add 0.34mL of sample into a sterile capped conical tube or other suitable sterile vessel.
3.2. Dilute to 10mL with LAL reagent water.
3.2.1. The sample preparation may be scaled to desired volume.
3.3. Enter specification of 2.5EU/mL.
3.4. Ensure all data is accurate before proceeding to load sample.
3.5. Load 25µL of sample in to each well and run test.
3.6. Ensure all suitability requirements meet specification.
3.7. Report result directly from instrument printout.

4. IDENTIFICATION CHLORIDE (USP<191>) — Meets Requirements:

4.1. Transfer 5mL of sample solution to a beaker.
4.2. To the sample solution add 1mL of 0.1N silver nitrate.
4.3. Mix thoroughly.

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4.4. A curdled, white precipitate is formed.
4.5. The precipitate is insoluble when 1 mL of concentrated Nitric acid is added but soluble when 6 mL of 6N Ammonium hydroxide is added.

5. IDENTIFICATION SODIUM (USP<191>) Meets Requirements:

5.1. Transfer 0.34mL of sample solution into a suitable beaker.
5.2. Add 2mL of purified water.
5.3. Add 2mL of 15% potassium carbonate and heat to a boil. No precipitate is formed.
5.4. Add 4mL of Potassium Pyroantimonate TS and heat to a boil.
5.5. Allow to cool in an ice bath, and if necessary, rub the inside of the test tube with a glass rod. A dense precipitate is formed to pass test.

6. MICROBIAL CONTENT TAMC ≤50 CFU/g; TYMC ≤150 CFU/g:

6.1. Package ~20g into a sterile container and send to an approved Outside Testing Facility. The analysis request form should include TAMC and TYMC. In order to pass the Total Aerobic Microbial Count must be ≤50CFU/g, the Total Yeast and Mold Count must be ≤150CFU/g.

7. TRACE METALS As, Cu, Fe, and Pb ≤2 ppm:

7.1. Refer to NexION 350X ICP-MS SOP for Instrument Set-Up and Use.
- 7.1.1. Sample Preparation:
- 7.1.2. General Notes:
  - 7.1.2.1. 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.
  - 7.1.2.2. Glass should be avoided as it has high potential for metal and mineral contaminations.
  - 7.1.2.3. Standard and sample solutions should be prepared in 50mL centrifuge tubes.
- 7.1.3. 1% Nitric Acid
  - 7.1.3.1. 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.
- 7.1.4. 15% Nitric Acid
  - 7.1.4.1. Dilute approximately 110 mL of Trace Metal Grade Nitric Acid to 500 mL with purified water.
  - 7.1.4.2. The solution is only used to rinse glassware and plasticware.
- 7.1.5. BioSpectra Daily Method:
  - 7.1.5.1. Sample Solutions:
    - 7.1.5.1.1. Weigh 0.10g of sample on an analytical balance. Add 100 µL of Environmental Standard Mix 6 and QS to 50.0 g with 1% Nitric Acid.
  - 7.1.5.2. Standard Curve Preparation:
    - 7.1.5.2.1. 2 ppm Stock
      - 7.1.5.2.1.1. Weigh 1.00 g of Instrument Calibration Standard 2 and QS to 50.0 g with 1% Nitric Acid.

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7.1.5.2.2. 100 ppb Stock
7.1.5.2.2.1. Weigh 2.50 g of 2 ppm Stock and QS to 50.0 with 1% Nitric Acid.
7.1.5.2.3. Blank
7.1.5.2.3.1. Pipette 100 µL of Environmental Standard Mix 6 into the centrifuge tube. QS to 50.0 g with 1% Nitric Acid.
7.1.5.2.4. 1 ppb Standard
7.1.5.2.4.1. 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.
7.1.5.2.5. 2 ppb Standard (also used as a Continuing Check Verification Sample (CCV))
7.1.5.2.5.1. 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.
7.1.5.2.6. 4 ppb Standard
7.1.5.2.6.1. 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.
7.1.5.2.7. 6 ppb Standard
7.1.5.2.7.1. Pipette 3.00 mL of the 100 ppb Stock, add 100 µL of Environmental Standard Mix 6 and QS to 50.0g with 1% Nitric Acid.

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

Sincerely,

Cassie Baun

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