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BIOSPECTRA

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SODIUM HYDROXIDE SOLUTION DEGRADATION AND IMPURITY REPORT

1. PURPOSE AND INTRODUCTION:

1.1. The impurity profiling of Sodium Hydroxide Solution was intended to identify and possibly quantify impurities found in the Sodium Hydroxide Solution manufactured at the BioSpectra Bangor, PA facility.

1.1.1. In the case where an impurity was found, a limit was set to the maximum allowable for establishing as pure of a product as possible. 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 analyses that were used to determine the presence of impurities and degradation products were as follows: Appearance and Color, Carbonate, Chloride, Identification (Sodium), Assay/Normality, and Trace Metals.

1.1.3. The three stages of the Sodium Hydroxide Solution Process that were analyzed were Raw Material (RM), Pre-Filtration (Pre), and Post Filtration or Finished Good (FG). A table was generated to include all sample results.

1.1.4. Each analysis in section 1.1.2 was tested at each stage of the process to determine any impurity or degradation product that may be present in the Sodium Hydroxide process, as well as which step the impurity was present, if at all.

2. SCOPE:

2.1. The degradation and impurity report applies to Sodium Hydroxide Solution that is produced at the BioSpectra Bangor, PA facility.

3. REFERENCES:

3.1. *USP Current*

3.2. Sodium Hydroxide 10N Testing Method, DCN:19-002773

3.3. Sodium Hydroxide 50% Testing Method, DCN: 19-002774

3.4. Degradation and Impurity Profiling SOP, DCN: 16-000373

3.5. Degradation and Impurity Profile Protocol: Sodium Hydroxide Solution, DCN:16-001972

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4. EQUIPMENT:

4.1. Analytical Balance
4.2. NexION 350X ICP-MS
4.3. HACH Portable Turbidimeter 2100Q

5. PROCEDURE:

5.1. All analyses were performed as per the current Sodium Hydroxide Testing Methods referenced in Section 3.

6. SPECIFICATION AND RESULTS:

SPECIFICATION TABLE					
Sample Identification	**Appearance and Color Specification**	**Carbonate Specification**	**Chloride Specification**	**Identification (Sodium) Specification**	**Assay/Normality Specification**
Raw Material	Monitor	Monitor	< 100 ppm	Passes Test	49.00-51.00%
Pre-Filtration Stage	Clear/Colorless Liquid	≤0.6%	≤ 5 ppm	Passes Test	9.9-10.1N
Finished Good (Post-Filtration Stage)	Clear/Colorless Liquid	≤0.6%	≤ 5 ppm	Passes Test	9.9-10.1N

TRACE METALS SPECIFICATIONS					
Sample Identification	**As**	**Cu**	**Fe**	**K**	**Pb**
Raw Material	Monitor	Monitor	< 3ppm	Monitor	Monitor
Pre-Filtration Stage	Monitor	Monitor	≤ 2ppm	Monitor	≤ 1ppm
Finished Good (Post-Filtration Stage)	Monitor	Monitor	≤ 2ppm	Monitor	≤ 1ppm

IMPURITY AND DEGRADATION ANALYSES					
Sample Identification	**Appearance and Color**	**Carbonate**	**Chloride**	**Identification (Sodium)**	**Concentration**
RMNH-052819	Clear, Colorless	0.06%	< 100 ppm	Passes Test	50.74 %
RMNH-060319	Clear and Colorless	0.03%	< 100ppm	Passes Test	50.63 %
NH4100-002-0519-PV Pre	Clear/Colorless Liquid	0.21%	< 5 ppm	Passes Test	10.00 N
NH4100-002-0519-PV FG Drum 1	Clear/Colorless Liquid	0.2%	< 5 ppm	Passes Test	10.05 N
NH4100-003-0519-PV Pre	Clear/Colorless Liquid	0.03%	< 5 ppm	Passes Test	10.02 N

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IMPURITY AND DEGRADATION ANALYSES					
Sample Identification	**Appearance and Color**	**Carbonate**	**Chloride**	**Identification (Sodium)**	**Concentration**
NH4100-003-0519-PV FG Drum 1	Clear/Colorless Liquid	0.03%	< 5 ppm	Passes Test	10.08 N
NH4100-004-0519-PV Pre	Clear/Colorless Liquid	0.04%	< 5 ppm	Passes Test	10.03 N
NH4100-004-0519-PV FG Drum 1	Clear/Colorless Liquid	0.04%	< 5ppm	Passes Test	10.03 N
NH4100-005-0619-PV Pre	Clear/Colorless Liquid	0.20%	< 5 ppm	Passes Test	10.05 N
NH4100-005-0619-PV FG Drum 1	Clear/Colorless Liquid	0.2%	< 5 ppm	Passes Test	10.03 N

TRACE METALS ANALYSIS					
Sample Identification	**As**	**Cu**	**Fe**	**K**	**Pb**
RMNH-052819	8.56 ppb	None Detected	629.40 ppb	62.46 ppm	None Detected
RMNH-060319	9.19 ppb	None Detected	604.28 ppb	62.72 ppm	None Detected
NH4100-002-0519-PV Pre	0.17 ppb	None Detected	< 2 ppm (388.23ppb)	24.92 ppm	< 1 ppm (ND)
NH4100-002-0519-PV FG Drum 1	5.34 ppb	None Detected	< 2 ppm (385.87ppb)	26.04 ppm	< 1 ppm (ND)
NH4100-003-0519-PV Pre	None Detected	None Detected	< 2 ppm (391.27ppb)	37.56 ppm	< 1 ppm (ND)
NH4100-003-0519-PV FG Drum 1	0.90 ppb	None Detected	< 2 ppm (369.64ppb)	38.22 ppm	< 1 ppm (ND)
NH4100-004-0519-PV Pre	2.45 ppb	None Detected	< 2 ppm (411.88ppb)	38.04 ppm	< 1 ppm (ND)
NH4100-004-0519-PV FG Drum 1	4.15 ppb	None Detected	< 2 ppm (293.84ppb)	38.73 ppm	< 1 ppm (ND)
NH4100-005-0619-PV Pre	None Detected	None Detected	< 2 ppm (471.70ppb)	37.70 ppm	< 1 ppm (ND)
NH4100-005-0619-PV FG Drum 1	4.24 ppb	None Detected	< 2 ppm (437.89ppb)	38.04 ppm	< 1 ppm (ND)

7. CONCLUSION:

7.1. Each sample analyzed met the required specifications for Sodium Hydroxide Solution Degradation and Impurity Protocol. It can be concluded that there are no identifiable impurities present in the Sodium Hydroxide Solution material at any stage of the process at this time.

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