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BIOSPECTRA

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DEGRADATION AND IMPURITY PROFILE REPORT: SODIUM DECANOATE 2021

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1. PURPOSE AND SCOPE:

1.1. The impurity profiling of Sodium Decanoate was intended to identify and possibly quantify impurities found in the product manufactured and purified at BioSpectra.

1.1.1. In the case where an impurity was found, a limit was set to the maximum allowable 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 was present or not (i.e. an identity test, which is qualitative and not quantitative.)

1.1.2. The three stages of the Sodium Decanoate process that were tested were the Raw Material, the Charged Solutions, and the Finished Good. The stage analyzed was dictated by the analysis required. The Finished Good sample was from the beginning drum sample from the first validation batch. Degradation and Impurity protocol testing was required on the first validation batch only.

1.1.3. Tables were generated to include all sample results in the Degradation and Impurity Profile Report.

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

1.1.4.1.1. Analyzed Raw Material and Finished Good Beginning Drum sample for Appearance.

1.1.4.2. Assay

1.1.4.2.1. Analyzed Raw Material and Finished Good Beginning Drum sample for Purity.

1.1.4.3. Identification (IR)

1.1.4.3.1. Analyzed Raw Material and Finished Good Beginning Drum sample for UATR identification.

1.1.4.4. Loss on Drying (LOD)

1.1.4.4.1. Analyzed Raw Material, Charged Solutions and Finished Good Beginning Drum sample for Loss on Drying.

1.1.4.5. pH (10%)

1.1.4.5.1. Analyzed Raw Material and Finished Good Beginning Drum sample. A basic result may indicate residual sodium hydroxide in the Raw Material. An acidic result may indicate residual decanoic acid.

1.1.4.6. Residual Solvents

1.1.4.6.1. The residual solvents testing was performed off site by an approved testing laboratory and was performed only on the Finished Good individual beginning drum sample. The analysis included Ethanol with a limit of 5000ppm max.

1.1.4.7. Single Impurities

1.1.4.7.1. Analyzed Raw Material and Finished Good Beginning Drum sample to evaluate unspecified impurities.

1.1.4.8. Solubility in Water

1.1.4.8.1. Analyzed Raw Material and Finished Good Beginning Drum sample for Solubility in Water.

1.1.4.9. Elemental Impurities, Iron, and Sodium Quantification

1.1.4.9.1. Analyzed Raw Material and Finished Good Beginning Drum sample

1.1.4.10. Water (KF)

1.1.4.10.1. Analyzed Raw Material and Finished Good Beginning Drum sample for Water (KF).

1.2. All results were recorded in the appropriate laboratory documentation. The results are detailed and analyzed in this report. This report includes all relevant data as well as references to the initial documented results. This report discusses any impurities found in the product and include a specification for any limits on the impurities found when applicable.

2. RESPONSIBILITIES:

2.1. Quality Control (QC) Management was responsible for control, implementation, training and maintenance of the protocol.

2.2. The QC Analysts were responsible for performing the testing stated in the protocol.

2.3. The QC compliance staff or qualified personnel was responsible for completing the degradation and impurity testing report and recording all results in the appropriate laboratory documentation.

3. REFERENCES:

3.1. *Current USP*

3.2. Degradation and Impurity Profiling SOP

3.3. Sodium Decanoate Testing Methods

3.4. Spectrum Two UATR

3.5. Degradation and Impurity Profile Protocol: Sodium Decanoate

4. PROCEDURE:

4.1. **APPEARANCE** :

Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the appearance testing are detailed in the table below:

Lot Number	Stage	Specification	Result
KS20181114	RM	White to off-white powder	White to Off-White Powder
NDEC-0121-0133-PV	FG Beginning Drum 1		White to Off-White Powder

4.2. **ASSAY** :

4.2.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the assay testing are detailed in the table below:

Lot Number	Stage	Specification	Result
KS20181114	RM	97.0-103.0%	99.34%
NDEC-0121-0133-PV	FG Beginning Drum 1	97.0-103.0%	100.33%

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4.3. **IDENTIFICATION (IR)** :

4.3.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the Identification (IR) testing are detailed in the table below:

Lot Number	Stage	Specification	Result
KS20181114	RM	Passes Test	Passes Test; 0.997094
NDEC-0121-0133-PV	FG Beginning Drum 1		Passes Test; 0.98038

4.4. **LOSS ON DRYING** :

4.4.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the loss on drying analysis are detailed in the table below:

Lot Number	Stage	Specification	Result
KS20181114	RM	Monitor	1.1833%
NDEC-0121-0133-PV Pre-Filtration	Charged Solutions		90.9595%
NDEC-0121-0133-PV Post-Filtration			99.8808%
NDEC-0121-0133-PV	FG Beginning Drum 1	3.0% max	2.6938%

4.5. **pH (10%)** :

4.5.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the pH (10%) analysis are detailed in the table below:

Lot Number	Stage	Specification	Result
KS20181114	RM	Monitor	9.747 @ 25.36°C
NDEC-0121-0133-PV	FG Beginning Drum 1	9.0-11.0	10.02 @ 24.0°C

4.6. **RESIDUAL SOLVENTS** :

4.6.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the Residual Solvents analysis are detailed in the table blow.

Lot Number	Stage	Specification	Result
NDEC-0121-0133-PV	FG Beginning Drum 1	<5000 ppm Ethanol	None Detected (< LOD 1.5ppm)

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4.7. SINGLE IMPURITIES :

4.7.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the single impurities analysis are detailed in the table below. All single impurities are ≤1.0%.

Lot Number	Stage	Specification	Result			
			Undecanoic Acid (C11)	Octanoic Acid	Nonanoic Acid	Total Impurities
KS20181114	RM	Monitor	0.14%	<0.04%	<0.05%	0.14%
NDEC-0121-0133-PV	FG Beginning Drum 1	≤1.0%	0.13%	<0.04%	<0.05%	0.13%

4.8. SOLUBILITY IN WATER :

4.8.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the solubility in water analysis are detailed in the table below.

Lot Number	Stage	Specification	Result
KS20181114	RM	Monitor	Passes Test
NDEC-0121-0133-PV	FG Beginning Drum 1	Passes Test	Passes Test

4.9. Elemental Impurities with Fe and Na Quantification USP < 232> < 233> and ICH Q3D:

Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the Elemental Impurities with Fe and Na Quantification are detailed in the table below.

Lot Number	Stage	Specification	Result		
			Elemental Impurities	Iron	Sodium
KS20181114	RM	Monitor	Complies	<2.49 ppm	111,000 ppm (11.10%)
NDEC-0121-0133-PV	FG Beginning Drum 1	Complies with USP <232><233> Report Iron and [1]Sodium	Complies	<2.49 ppm	111,700 ppm (11.17%)

[1]Sodium Range= 10.65 - 13.02%.

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4.10. **WATER (KARL FISCHER)** :

4.10.1. Refer to the Degradation and Impurity Profile Protocol: Sodium Decanoate for testing methods and requirements. The results of the water by Karl Fischer analysis are detailed in the table below.

Lot Number	Stage	Specification	Result
KS20181114	RM	Monitor	1.37%
NDEC-0121-0133-PV	FG Beginning Drum 1	1.5 – 3.0%	2.75%

5. CONCLUSION:

5.1. All samples met the required specifications for each analysis, as dictated by the Degradation and Impurity Profile Protocol: Sodium Decanoate, DCN: 18-002524.

5.2. It is conclusive that there are no unintentionally introduced impurities present in the manufacturing process of Sodium Decanoate Bio Excipient material at any stage, as currently validated.