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SODIUM DECANOATE REAL TIME STABILITY REPORT: 2018 LOTS

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1. OVERVIEW:

The purpose of this report is to analyze and conclude on the data obtained from the real-time stability study of Sodium Decanoate manufactured in 2018 the Bangor, PA facility of BioSpectra. Testing intervals are designated by T_n , where n equals the number of months on stability. Testing is performed every three months for the first year, every six months for the second year, and annually for each subsequent year in order to maintain that the manufactured product remains stable under the specified conditions and for the specified interval of time. The analysis of the compiled data may also aid in a re-evaluation of the retest date for the finished good product.

This Real Time Stability analysis will assess the stability of Sodium Decanoate validation lots ND3200-009-0918-PV, ND3200-010-1018-PV, ND3200-011-1018-PV, and Sodium Decanoate lot ND3200-014-1018 that completed thirty-six (36) months of real-time stability in October 2021. This study includes the following analyses: Appearance, Solubility in Water, Assay, Loss on Drying (LOD), Single Impurities, Quantitative Impurities, Identification (IR), and Water by Karl Fischer (KF). Results from all analyses are summarized in Table 2 and Table 3.

2. REFERENCES:

- 2.1. BSI-SOP-0136, Stability Testing Program
- 2.2. BSI-SOP-0146, Stability Inventory
- 2.3. Current USP
- 2.4. ICH Q1

3. SAMPLE DESIGNATION:

- 3.1. Samples initially placed on the stability program consisted of three lots of Sodium Decanoate placed in cold storage conditions (Lots: ND3200-009-0918-PV, ND3200-010-1018-PV, and ND3200-011-1018-PV), and then a fourth lot was placed in ambient storage conditions (ND3200-014-1018). Stability samples from all of these lots were put into 2P/P and Labline packaging configuration. The samples were packaged in accordance with the Stability Inventory SOP. Reference Table 1, below, for packaging configurations and descriptions. The type of packaging utilized in this stability study was based on BioSpectra packaging offered to the customer.

TABLE 1: PACKAGING DETAILS	
Packaging Configuration	Packaging Description
2 Poly/Poly (2P/P)	Samples are individually placed into small polyethylene bags and are sealed with a zip tie. All individual bags are then placed into a single polyethylene bag, sealed with a zip tie, and that bag is placed in to a poly pail and sealed.
Labline (HDPE Bottle)	Samples are packaged into a HDPE Lab Screw-Top Bottle.

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4. STORAGE:

- 4.1. The Packaging and Storage requirements for Sodium Decanoate are to be in tightly closed container stored at refrigerated conditions between 2 to 8°C. Lots ND3200-009-0918, ND3200-010-1018-PV, and ND3200-011-1018-PV were stored in Refrigerated Storage Container A01RC02. This unit was originally qualified with an allowable range of 2°C ±5, which was then changed to 2 – 8°C. The temperature was monitored consistently using Tempmate single use data loggers, which record for 110 days. The samples were placed into the storage container in October 2018 and remained until May 2021. The maximum temperature recorded was 29.3°C, the minimum temperature was -5.8°C, the average temperature was 5.2°C, and the Mean Kinetic Temperature was 5.6°C. Section 5 will include any excursions from these conditions that could not be explained by the entrance and exit logbook.
- 4.2. In May 2021, the samples were moved to refrigeration unit A01RC04 due to temporary operating instruction BTOI21-84, which was a result of BDI21-259. They remained in this Refrigerated Storage Container until the last set of samples for this study were pulled (T=36) in October 2021. The maximum temperature recorded was 25.4°C, the minimum temperature was -1.1°C, the average temperature was 6.0°C, and the Mean Kinetic Temperature was 6.0°C. Section 5 will include any excursions from these conditions that could not be explained by the entrance and exit logbook.
- 4.3. Lot ND3200-014-1018 was stored at room temperature. The samples were initially placed in the Zone M Warehouse from October 2018 until September 2019, which is controlled for temperature from 10 – 40°C and relative humidity is monitored. The temperature was monitored continuously using MadgeTech data loggers. The maximum temperature recorded was 31.6°C, the minimum temperature was 12.3°C, the average temperature was 23.6°C, and the Mean Kinetic Temperature was 25.2°C. Section 5 will include any excursions from these conditions that could not be explained by the entrance and exit logbook.
- 4.4. On September 25, 2019, the room temperature stability samples from Lot ND3200-014-1018 were relocated from the Zone M Warehouse to the Long-Term Stability Chamber (LTS Chamber) due to the inability to control the temperature of the warehouse during the summer months. They remained in the Long-Term Stability Chamber until the last set of samples for this study were pulled (T=36) in October 2021. The temperature and humidity is monitored continuously using MadgeTech data loggers, with an allowable temperature range of 25°C ±2 and relative humidity range of 60% ±5. The maximum temperature recorded was 27.8°C, the minimum temperature was 21.8°C, the average temperature was 25.5°C, and the Average Mean Kinetic Temperature was 25.5°C. The maximum relative humidity recorded was 72.4%, the minimum relative humidity was 30.3%, and the average relative humidity was 61.7%. Maximum and minimum values that are outside limits for temperature and humidity are due to opening the door of the chamber as explained in Temperature and Humidity Monitoring Assessments for the chambers. Section 5 will include any excursions from these conditions that could not be explained by the entrance and exit logbook.

5. INVESTIGATIONS:

- 5.1. BLI19-01: OOS Assay results were obtained for multiple T=3 interval Sodium Decanoate samples. It was determined that the Perchloric Acid 0.1N Solution used to titrate the samples has a large thermal expansion that will occur based on temperature. Standardization and sample analysis must be performed at the same controlled temperature. Samples were re-tested and met specification.
- 5.2. BLI19-38: OOS Assay results were obtained for ND3200-010-1018-PV T=12 2P/P and Labline samples. Elevated results attributed to analyst error. Samples were re-tested and met specification.

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- 5.3. BDI18-79: Pre-Filtration samples for ND3200-011-1018-PV were more turbid than the specification allowed for. The Post-Filtration samples met the specification, which proved that the process reduces the turbidity significantly. It was determined that there is no risk to the material.
- 5.4. BDI18-82: A Planned Deviation was issued for T0 testing for batches ND3200-009-0918-PV and ND3200-010-1018-PV. The samples were unable to be tested, as the Stability Indication Protocol was not finalized prior to the 5 allowed business days from the sample submission date.
- 5.5. BDI18-83: The time between swirls performed on batch ND3200-011-1018-PV was not within the required 3 ± 1 hours. The shorter time between swirls was determined not to have an impact on the material.
- 5.6. BDI18-89: ND3200-014-1018 T0 pH 10% was performed incorrectly and was invalidated. Due to the invalidation, the T0 testing was unable to be performed within the allowable time frame of 5 business days.
- 5.7. BDI18-91: Temperature excursions were recorded in A01RC02 on 8/23/18 and 9/8/18. The excursions could not be justified by reviewing the logbook. These temperature excursions had no effect on the material, as all T3 samples were tested and met requirements.
- 5.8. BDI18-92: Zone M Warehouse temperature and humidity data was unable to be downloaded from the data loggers for various days between 8/24/18 and 11/8/18. There was no effect on the material, as T3 was tested and met requirements.
- 5.9. BDI18-97: Zone M Warehouse Madgetech data loggers were not replaced prior to their calibration due date. There were no temperature excursions recorded during the time the loggers were out of calibration (10/4/18 – 11/15/18). There was no effect on the material, as T3 was tested and met requirements.
- 5.10. BDI20-170: Cold Storage temperature data was not recorded on the Temperature and Humidity Monitoring Assessment form from end of 2019-2020. There was no impact to any samples.
- 5.11. BDI20-201: Temperature excursions were recorded in A01RC02 from 07/31/20 to 11/17/20. The excursions could not be justified by reviewing the logbook. It was determined that there was no impact to any samples.
- 5.12. BDI21-259: Temperature excursions were recorded in A01RC04 on 07/09/21. The excursion could not be justified by reviewing the logbook. It was determined that there was no impact to any samples.
- 5.13. BDI22-193: This investigation was issued to address missing Tempmate data for A01RC04 from Feb 2021-Oct 2021, and is due on 8/31/22.

6. LOT EVALUATION:

TABLE 2A: ND3200-009-0918-PV 2P/P									
Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	101.85	102.93	102.91	102.49	102.44	102.92	102.83	102.73
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	1.3861	1.8720	2.0824	1.8995	2.0859	1.9295	1.9347	2.2251
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	1.73	2.01	2.15	2.27	2.35	2.27	2.27	2.48

TABLE 2B: ND3200-009-0918-PV LABLINE									
Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	101.85	102.67	102.78	102.54	102.50	102.97	102.76	102.71
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	1.3861	1.8015	1.8105	1.8637	1.8779	1.8800	2.1720	2.3990
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	1.73	1.95	1.79	2.24	2.24	2.12	2.43	2.69

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TABLE 2C: ND3200-010-1018-PV 2P/P

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	102.11	102.79	102.84	102.93	102.44	103.01	103.01	102.99
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	1.8119	2.1384	2.2932	2.1904	2.2826	2.1527	2.1956	2.5079
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	2.23	2.33	2.45	2.58	2.58	2.62	2.56	2.63

TABLE 2D: ND3200-010-1018-PV LABLINE

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	102.11	102.85	103.04	102.98	102.70	102.82	103.02	102.94
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	1.8119	2.1385	2.2572	2.2694	2.1834	2.1417	2.2273	2.5965
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	2.23	2.34	2.37	2.66	2.50	2.60	2.57	2.79

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TABLE 2E: ND3200-011-1018-PV 2P/P									
Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	101.74	102.52	102.93	103.03	102.55	102.74	102.30	102.79
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	2.1195	1.9755	2.2334	2.1178	2.2198	2.2008	2.0715	2.3808
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	2.16	2.21	2.28	2.45	2.80	2.40	2.56	2.55

TABLE 2F: ND3200-011-1018-PV LABLINE									
Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	101.74	102.63	102.24	102.35	102.41	102.79	102.08	102.67
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	2.1195	1.8915	2.3119	2.0709	2.3834	2.2057	2.0969	2.2975
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	2.16	2.13	2.48	2.39	2.68	2.45	2.56	2.61

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TABLE 2G: ND3200-014-1018 2P/P									
Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	102.67	102.54	102.32	102.13	102.85	102.79	102.60	101.71
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	1.9952	2.1007	2.0688	2.2744	2.3850	2.5589	2.6131	2.8149
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	2.21	2.26	2.42	2.59	2.64	2.75	2.92	2.88

TABLE 2H: ND3200-014-1018 LABLINE									
Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Appearance	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder	White to Off-White Powder
Assay	97.0 – 103.0%	102.67	102.53	102.52	102.41	102.55	102.72	102.59	102.20
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
LOD	3.0% Max	1.9952	2.1064	2.1169	2.3530	2.4308	2.5226	2.4552	2.4811
Single Impurities	<1.0% Max	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5 – 3.0%	2.21	2.22	2.44	2.71	2.72	2.70	2.79	2.80

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TABLE 3: QUANTITATIVE IMPURITIES

Quantitative Impurities data for T=6 through T=36 for the lots stored in Cold Storage and T=9 through T=36 for Room Temperature/LTS Storage. Earlier lots not were not tested via this method. Results can be found in MEMO21-1258.

TABLE 3A: ND3200-009-0918-PV 2P/P				
Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=6	0.12	0.18	<0.1%	0.30
T=9	0.12	0.16	<0.1%	0.28
T=12	0.11	0.17	<0.1%	0.28
T=18	0.10	0.15	<0.1%	0.25
T=24	0.13	0.19	<0.1%	0.32
T=36	<0.1%	0.11	<0.1%	0.11

TABLE 3B: ND3200-009-0918-PV LABLINE				
Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=6	0.12	0.17	<0.1%	0.29
T=9	0.11	0.15	<0.1%	0.26
T=12	0.11	0.17	<0.1%	0.28
T=18	0.11	0.15	<0.1%	0.26
T=24	0.12	0.18	<0.1%	0.30
T=36	<0.1%	<0.1%	<0.1%	<0.1%

TABLE 3C: ND3200-010-1018-PV 2P/P				
Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=6	0.13	0.16	<0.1%	0.29
T=9	0.12	0.14	<0.1%	0.26
T=12	0.12	0.15	<0.1%	0.27
T=18	0.10	0.13	<0.1%	0.23
T=24	0.13	0.17	<0.1%	0.30
T=36	<0.1%	0.10	<0.1%	0.10

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TABLE 3D: ND3200-010-1018-PV LABLINE

Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=6	0.13	0.16	<0.1%	0.29
T=9	0.12	0.13	<0.1%	0.25
T=12	0.12	0.16	<0.1%	0.28
T=18	0.10	0.13	<0.1%	0.23
T=24	0.13	0.17	<0.1%	0.30
T=36	<0.1%	<0.1%	<0.1%	<0.1%

TABLE 3E: ND3200-011-1018-PV 2P/P

Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=6	0.19	0.20	<0.1%	0.39
T=9	0.17	0.17	<0.1%	0.34
T=12	0.18	0.19	<0.1%	0.37
T=18	0.17	0.18	<0.1%	0.35
T=24	0.19	0.21	<0.1%	0.40
T=36	0.13	0.13	<0.1%	0.26

TABLE 3F: ND3200-011-1018-PV LABLINE

Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=6	0.19	0.20	<0.1%	0.39
T=9	0.17	0.17	<0.1%	0.34
T=12	0.18	0.19	<0.1%	0.37
T=18	0.17	0.18	<0.1%	0.35
T=24	0.20	0.21	<0.1%	0.41
T=36	0.11	0.12	<0.1%	0.23

TABLE 3G: ND3200-014-1018 2P/P

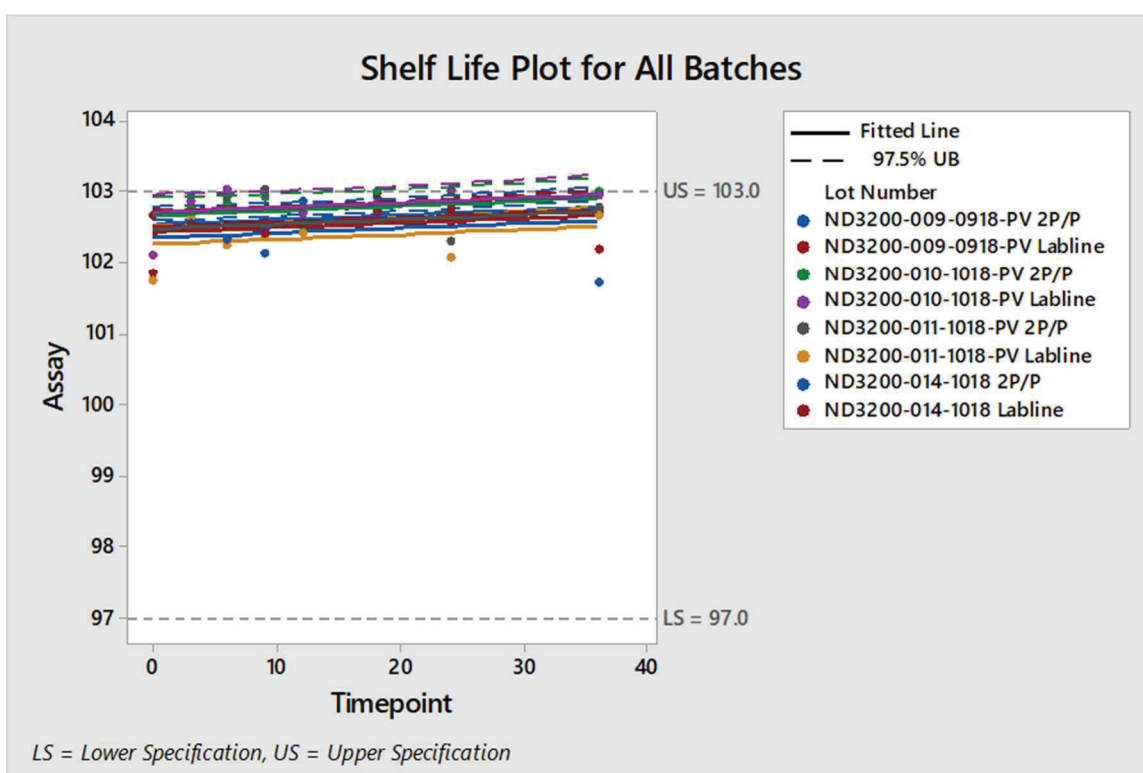
Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=9	0.13	0.13	<0.1%	0.26
T=12	0.13	0.14	<0.1%	0.27
T=18	0.13	0.14	<0.1%	0.27
T=24	0.14	0.16	<0.1%	0.30
T=36	0.10	0.11	<0.1%	0.22

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TABLE 3H: ND3200-014-1018 LABLINE

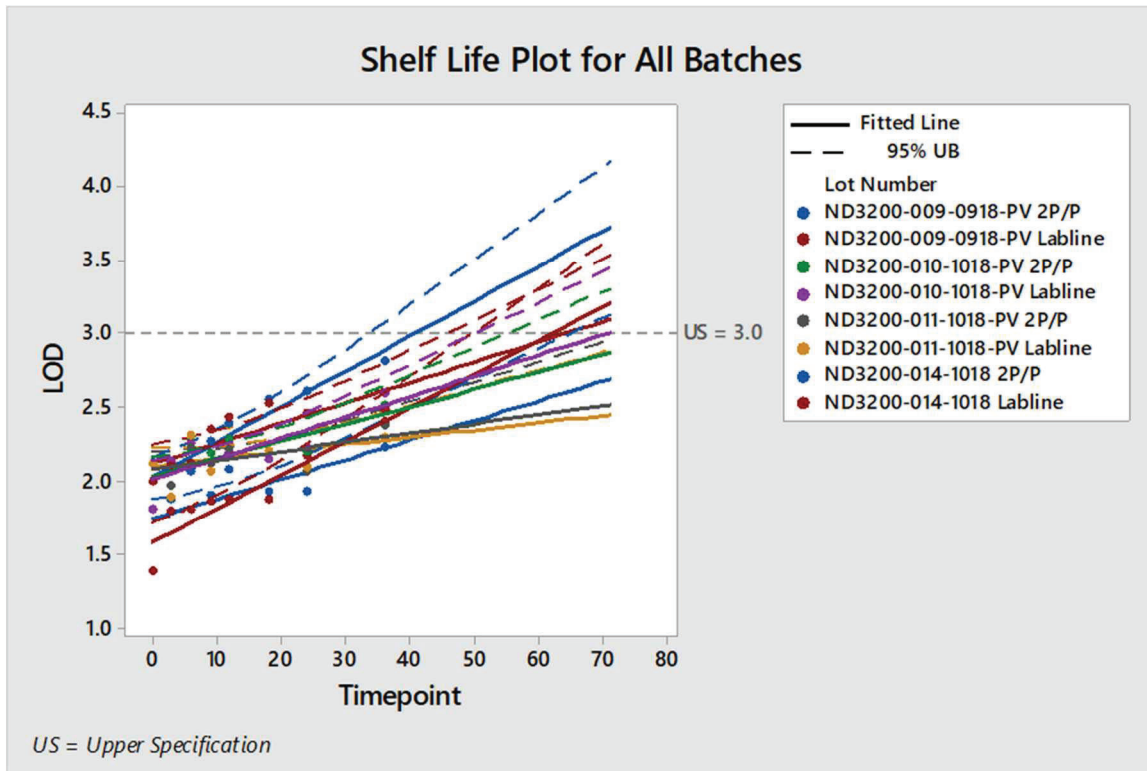
Interval	Impurities			
	Sodium Octanoate %	Sodium Nonanoate %	Unspecified Single Impurities %	Total Impurity %
T=9	0.12	0.12	<0.1%	0.24
T=12	0.13	0.14	<0.1%	0.27
T=18	0.13	0.14	<0.1%	0.27
T=24	0.15	0.16	<0.1%	0.31
T=36	0.11	0.11	<0.1%	0.22

GRAPH 1: ASSAY

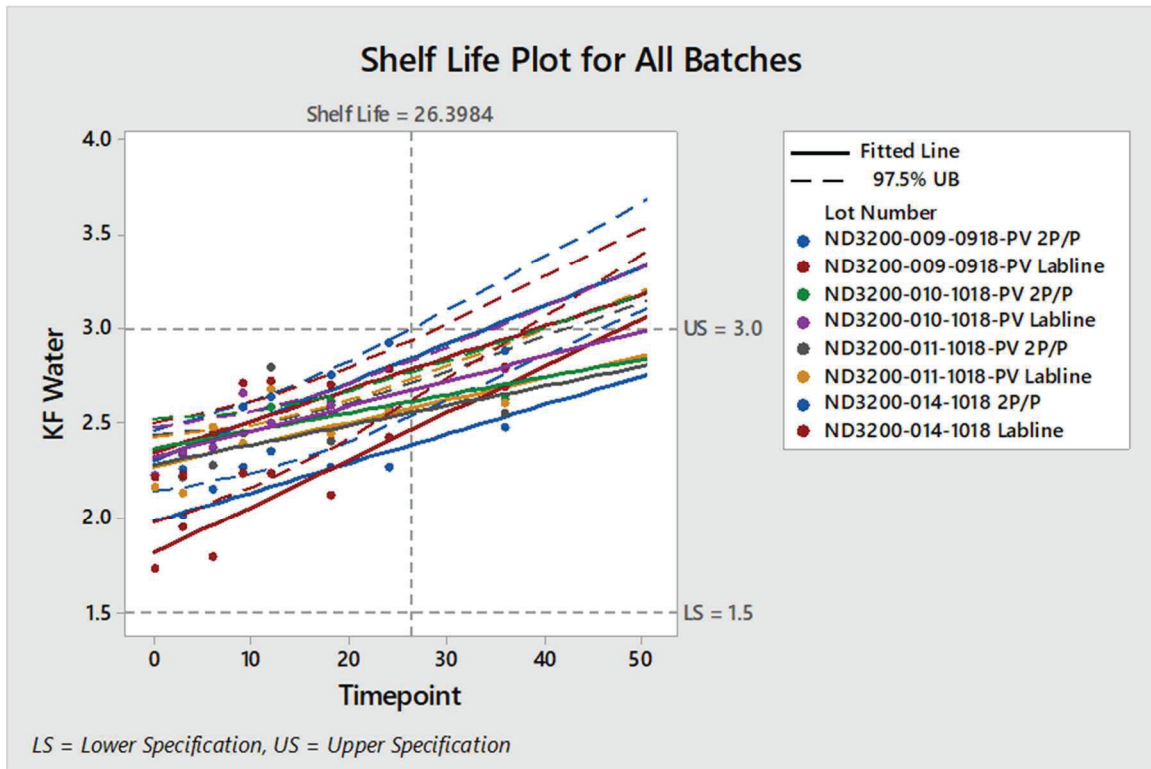


The No Shelf-Life was able to be determined for Assay, as the mean response slope is not significantly different from zero using 95% confidence. There is no impact to the product or currently assigned retest period of this material.

GRAPH 2: LOSS ON DRYING (LOD)



The No Shelf-Life was able to be determined for Loss on Drying (LOD), as the mean response slope is not significantly different from zero using 95% confidence. There is no impact to the product or currently assigned retest period of this material.

GRAPH 3: WATER BY KARL FISCHER (KF)

The predicted Shelf-Life for Water by Karl Fischer (KF) was determined to be 26.3984 months as of the T=36 month time interval. This is the last time interval for this study.

7. CONCLUSION:

- 7.1. In regards to the Real Time Stability Study for Sodium Decanoate, all data met the specifications set forth in the Stability Testing Program for all three lots stored at the recommended refrigerated condition and for the lot stored in the ambient temperature conditions which simulates a standard room temperature storage conditions. In accordance with ICH Q1E 2.4.2.1, the retest date may be proposed for up to 1.5x in regards to samples stored at refrigerated temperatures, where x is the period covered by long term stability data, but should be no more than 6-months beyond. The Real Time Stability Study data, along with the predicted shelf-life plots, supports the current retest date of 24 months for lots of Sodium Decanoate manufactured at BioSpectra in the Bangor, PA facility. The predicted shelf-life plot for Water by Karl Fischer is the limiting factor for this determination.
- 7.2. The lot stored at standard room temperature shows that the Sodium Decanoate material can remain within specifications at temperatures greater than the recommended cold storage. In accordance with ICH Q1E 2.4.2.1, the retest data may be proposed for up to 2x, where x is the period covered by long-term stability data, but should be no more than 12 months beyond. However, this period of time would be greater than the retest date calculated from the cold storage data and the predicted shelf-life plot. The shortest of the two retest dates should be used to determine a retest date as per ICH guidelines.

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8. STATEMENT OF COMMITMENT:

- 8.1. BioSpectra is responsible for the following regarding Stability Data in this report:
 - 8.1.1. In the event that any stability analysis produces results found to be out of specification, the batch produced immediately before and after will be tested in full and analyzed in comparison with the batch in question.
- 8.2. This will serve to provide information to effectively ensure that the root cause of the investigation has not impacted the batch manufactured before or after the batch in question.
 - 8.2.1. If a stability analysis is found to be out of specification, the batch will be withdrawn from the market through communication with the customer. Additionally, an investigation will be conducted to determine the possible withdrawal of the batches produced before and after the batch in question.
- 8.3. In the event that any out of specification results are confirmed, all authorized users of the material will be notified.



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Approval:	<table border="1"> <thead> <tr> <th>Approvers</th> <th>Date</th> <th>Time</th> <th>Group</th> <th>Name</th> </tr> </thead> <tbody> <tr> <td></td> <td>09-Feb-2021</td> <td>02:15:31 PM</td> <td>EDITOR</td> <td>Bertsch, Amy M</td> </tr> <tr> <td></td> <td>09-Feb-2021</td> <td>04:21:31 PM</td> <td>QUALITY</td> <td>Hall, Zachary J</td> </tr> <tr> <td></td> <td>09-Feb-2021</td> <td>05:08:36 PM</td> <td>SNR MGMT</td> <td>Miller, Jenna M</td> </tr> </tbody> </table>				Approvers	Date	Time	Group	Name		09-Feb-2021	02:15:31 PM	EDITOR	Bertsch, Amy M		09-Feb-2021	04:21:31 PM	QUALITY	Hall, Zachary J		09-Feb-2021	05:08:36 PM	SNR MGMT	Miller, Jenna M
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Sodium Decanoate Real-Time Stability Report: Ambient Storage

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1. OVERVIEW:

The purpose of this report is to analyze the data obtained from the Real-Time Stability of Sodium Decanoate lots stored at ambient temperatures in the BioSpectra's Bangor, PA facility. Two lots of Sodium Decanoate were placed on the Stability Testing Program in October 2018 and January 2019 to evaluate the quality of the material when stored in ambient conditions versus the recommended cold storage conditions. The long-term Real-Time Stability Program consists of testing every three months for the first year, every six months for the second year, and annually for each subsequent year, noted as T_n where n represents the number of months on stability. Analysis has been conducted for a total of 24 months and the material will continue on the stability program until 36 months of data has been obtained, in order to assure that the manufactured material remains stable under the specified conditions and for the specified interval of time. The analysis of the compiled data may be used to re-evaluate the currently assigned re-test period for Sodium Decanoate material, and the currently required storage conditions.

2. REFERENCES:

- 2.1. Current USP
- 2.2. ICH Q1
- 2.3. [Stability Testing Program](#)
- 2.4. [Stability Inventory](#)

3. SAMPLE DESIGNATION:

Samples placed on the Stability Testing Program consisted of two lots of Sodium Decanoate. Stability samples from each of the batches were separated into two different packaging configurations, as dictated by the packaging configurations offered to BioSpectra customers. Refer to Table 1 below for packaging configurations and descriptions.

Table 1: Packaging Configurations

Packaging Configurations	Description of Packaging Configurations
2 Poly/Poly (2P/P)	Samples are individually placed into small poly bags and are sealed with a ziptie. All samples are placed into a second poly bag, sealed with a ziptie, and are then placed into a poly pail and sealed.
Lab Screw-Top Bottle (Labline)	Samples are individually placed into Lab Screw-Top Bottles and are sealed with tamper evident lids.

4. STORAGE:

The two lots of Sodium Decanoate that were placed on stability in October 2018 and January 2019 are being stored in ambient storage conditions. The samples were initially placed in the Zone M Warehouse. Due to the inability to control the temperature of the warehouse

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during the summer months, the stability samples were relocated to the long-term stability chamber. From October 2018 through September 25, 2019 the samples were stored in the Zone M Warehouse. The temperature was monitored continuously using MadgeTech data loggers. The minimum temperature of the warehouse during this timeframe was 12.25°C. The maximum temperature of the warehouse during this timeframe was 33.67°C.

On September 25, 2019, all ambient temperature stability samples were relocated from the Zone M Warehouse to the long-term Stability Chamber. The remaining samples are still being stored in this location. The temperature is monitored continuously using MadgeTech data loggers, with an allowable temperature range of 23°C – 27°C. The minimum temperature reached during the study thus far was 23.97°C and the maximum temperature reached during the study thus far was 27.72°C. The maximum temperature was out of specification for less than one hour and the humidity remained within specification during this time. No discrepancy was issued for this excursion.

5. INVESTIGATIONS

BDI18-89: ND3200-014-1018 T₀ pH 10% was performed incorrectly and was invalidated. Due to the invalidation, the T₀ testing was unable to be performed within the allowable timeframe of 5 business days.

BDI18-92: Zone M Warehouse temperature and humidity data was unable to be downloaded from the data loggers for various days between 8/24/18 and 11/8/18. There was no effect on the material, as ND3200-014-1018 T₃ was tested and met requirements.

BDI18-97: Zone M Warehouse Madgetech data loggers were not replaced prior to their calibration due date. There were no temperature excursions recorded during the time the loggers were out of calibration (10/4/18 – 11/15/18). There was no effect on the material, as ND3200-014-1018 T₃ was tested and met requirements.

LOT ANALYSIS:

Table 2: All Inclusive Data Table

Sodium Decanoate Real-Time Stability Data										
Lot Number	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
ND3200-014-1018-Labline	Appearance	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder
	Assay	97.0 – 103.0%	102.67%	102.53%	102.52%	102.41%	102.55%	102.72%	102.59%	Future Pull Date: 10/22/21
	IR	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	LOD	3.0% max	1.9952%	2.1064%	2.1169%	2.3530%	2.4308%	2.5226 %	2.4552%	
	Single Impurities	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	
	Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	Water (KF)	1.5 – 3.0%	2.21%	2.22%	2.44%	2.71%	2.72%	2.70%	2.79%	
ND3200-014-1018-2P/P	Appearance	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	
	Assay	97.0 – 103.0%	102.67%	102.54%	102.32%	102.13%	102.85%	102.79%	102.60%	

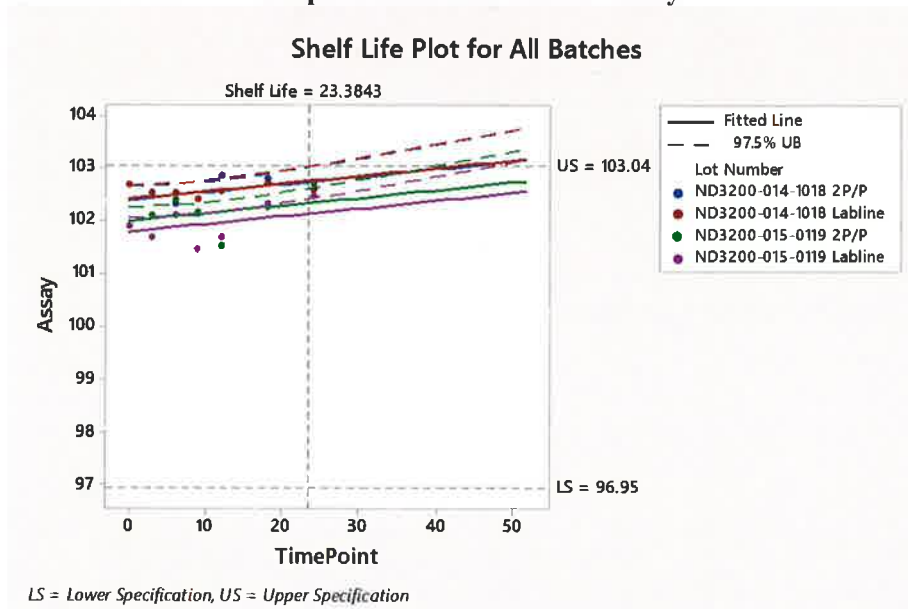
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Sodium Decanoate Real-Time Stability Data										
Lot Number	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
	IR	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	LOD	3.0% max	1.9952%	2.1007%	2.0688%	2.2744%	2.3850%	2.5589%	2.6131%	
	Single Impurities	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	
	Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	Water (KF)	1.5 – 3.0%	2.21%	2.26%	2.42%	2.59%	2.64%	2.75%	2.92%	
ND3200-015-0119 Labline	Appearance	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	Future Pull Date: 1/17/22
	Assay	97.0 – 103.0%	101.91%	101.69%	102.12%	101.47%	101.69%	102.33%	102.46%	
	IR	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	LOD	3.0% max	1.4246%	1.8038%	1.7142%	1.7126%	1.7617%	2.3568%	2.6262%	
	Single Impurities	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	
	Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	Water (KF)	1.5 – 3.0%	1.63%	2.03%	1.92%	1.93%	1.99%	2.60%	2.65%	
ND3200-015-0119 2P/P	Appearance	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	White to Off-white Powder	Future Pull Date: 1/17/22
	Assay	97.0 – 103.0%	101.91%	102.11%	102.41%	102.18%	101.54%	102.25%	102.71%	
	IR	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	LOD	3.0% max	1.4246%	1.5949%	1.5398%	2.1977%	2.3954%	2.0422%	2.5580%	
	Single Impurities	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	<1.0%	
	Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	
	Water (KF)	1.5 – 3.0%	1.63%	1.85%	1.75%	2.31%	2.52%	2.39%	2.62%	

Shelf Life Plots have been created for all quantitative results, excluding single impurities via GC. Due to the nature of reporting for single impurities, there is no variance in results and it can therefore not be used to determine an estimated shelf life. For analyses with a specification of maximum value only, no Lower Specification value was included in the Shelf Life Plots. This is only applicable to Loss on Drying.

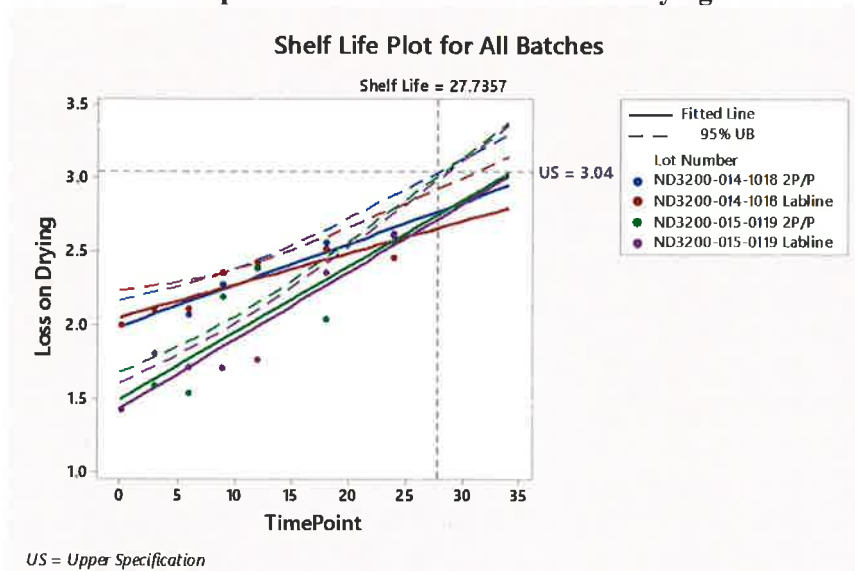
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Graph 1: Shelf Life Plot for Assay



The predicted shelf life for Assay was determined to be 23.3843 months. The Shelf Life is defined as the time period in which you may be 95% confident that at least 50% of response is within the required limits of specification. All data up to 24 months has met the required specifications. There is no risk to the currently assigned shelf-life of 24 months, as the material is currently meeting requirements, but is at the top end of the specification. The assay results will continue to be monitored through the rest of the stability study, and the re-test period will be re-evaluated at the conclusion of the 36-month study.

Graph 2: Shelf Life Plot for Loss on Drying

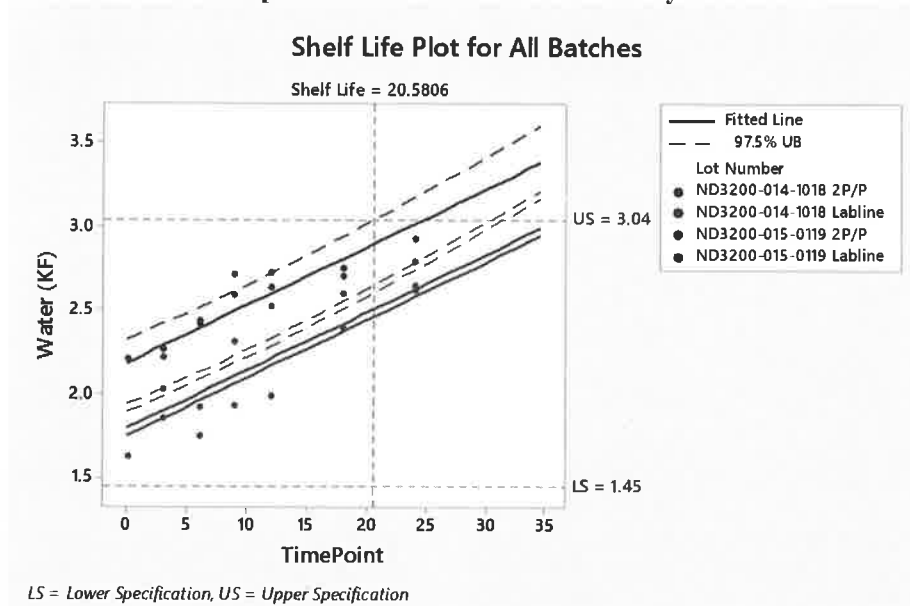


The predicted shelf life for Loss on Drying was determined to be 27.7357 months. The Shelf Life is defined as the time period in which you may be 95% confident that at least 50% of response is within the required limits of specification. All data up to 24 months has met the required specifications. There is no

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risk to the currently assigned shelf-life of 24 months, as the material continues to meet requirements, though is trending toward the top end of the specification. The Loss on drying results will continue to be monitored through the rest of the stability study, and the re-test period will be re-evaluated at the conclusion of the 36-month study.

Graph 3: Shelf Life Plot for Water by KF



The predicted shelf life for Water by Karl Fischer was determined to be 20.5806 months. The Shelf Life is defined as the time period in which you may be 95% confident that at least 50% of response is within the required limits of specification. All data up to 24 months has met the required specifications. There is no risk to the currently assigned shelf-life of 24 months, as the material continues to meet requirements, though is trending toward the top end of the specification. The Water by KF results will continue to be monitored through the rest of the stability study, and the re-test period will be re-evaluated at the conclusion of the 36-month study.

6. CONCLUSION:

All data obtained from stability testing thus far is meeting the criteria set forth in the Stability Testing Program. In accordance with ICH Q1E 2.4.2.1, the retest date may be proposed for up to $2x$, where x is the period covered by long term stability data, but should be no more than 12-months beyond. Based on the results obtained in this study compared to the results obtained in the Sodium Decanoate Cold Storage study, it has been determined that there is no risk to Sodium Decanoate material when stored under ambient conditions. Due to the predicted shelf life plots for Assay, Loss on Drying, and Water by Karl Fischer, a retest date will be evaluated at the conclusion of the 36-month stability study. Results will continue to be monitored at the T_{36} timepoint.

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 - If a stability analysis is found to be out of specification, the batch will be withdrawn from the market through communication with the Applicant and any additional customer. Additionally, an investigation will be conducted to determine the possible withdrawal of the batches produced before and after the batch in question.
 - In the event that any out of specification results are confirmed, all authorized users of the material will be notified.

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