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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 T<sub>0</sub> pH 10% was performed incorrectly and was invalidated. Due to the invalidation, the T<sub>0</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> was tested and met requirements.

## LOT ANALYSIS:

**Table 2: All Inclusive Data Table**

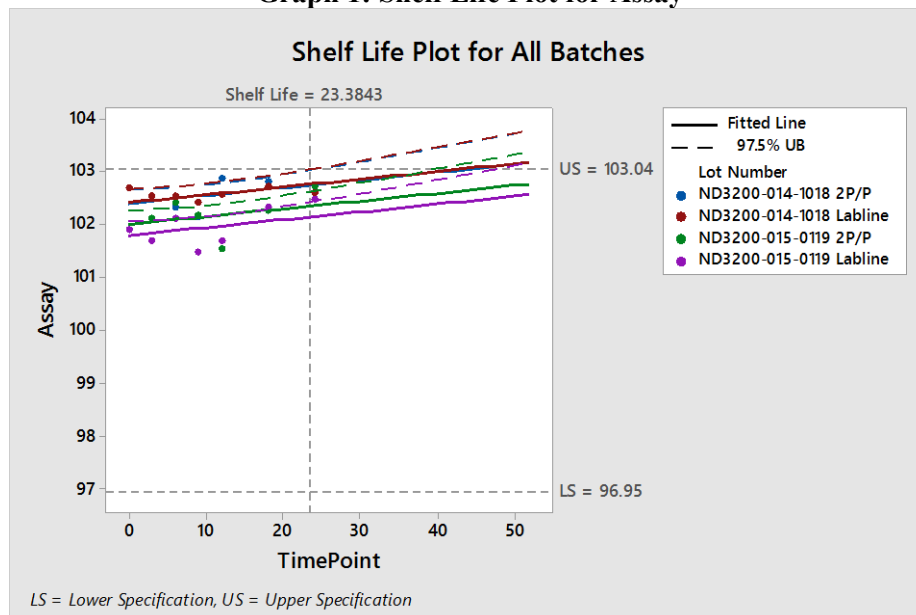
Sodium Decanoate Real-Time Stability Data										
Lot Number	Analysis	Specification	T <sub>0</sub>	T <sub>3</sub>	T <sub>6</sub>	T <sub>9</sub>	T <sub>12</sub>	T <sub>18</sub>	T <sub>24</sub>	T <sub>36</sub>
ND3200-014-1018-Labline	Appearance	White to Off-white Powder	White to Off-white Powder	White 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	Future Pull Date: 10/22/21
	Assay	97.0 – 103.0%	102.67%	102.53%	102.52%	102.41%	102.55%	102.72%	102.59%	
	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	Future Pull Date: 10/22/21
	Assay	97.0 – 103.0%	102.67%	102.54%	102.32%	102.13%	102.85%	102.79%	102.60%	

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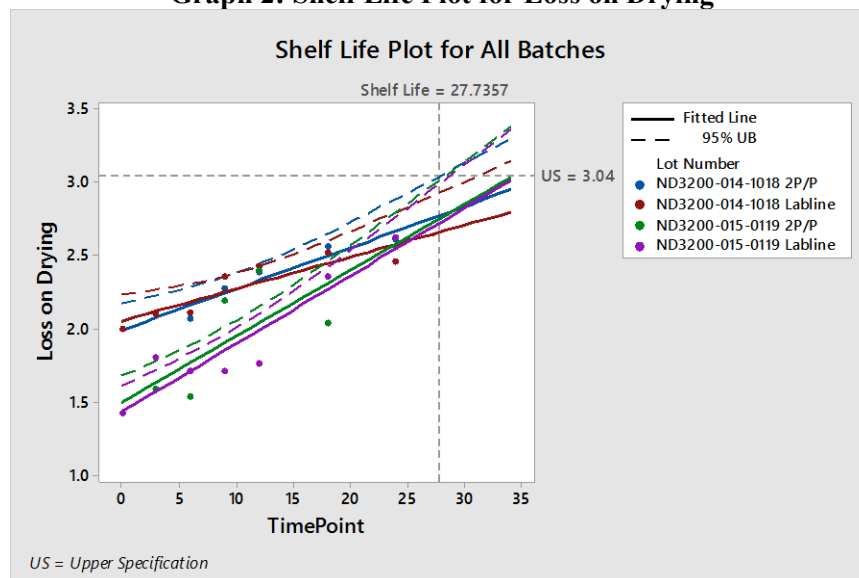
Sodium Decanoate Real-Time Stability Data										
Lot Number	Analysis	Specification	T <sub>0</sub>	T <sub>3</sub>	T <sub>6</sub>	T <sub>9</sub>	T <sub>12</sub>	T <sub>18</sub>	T <sub>24</sub>	T <sub>36</sub>
	IR	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes 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.

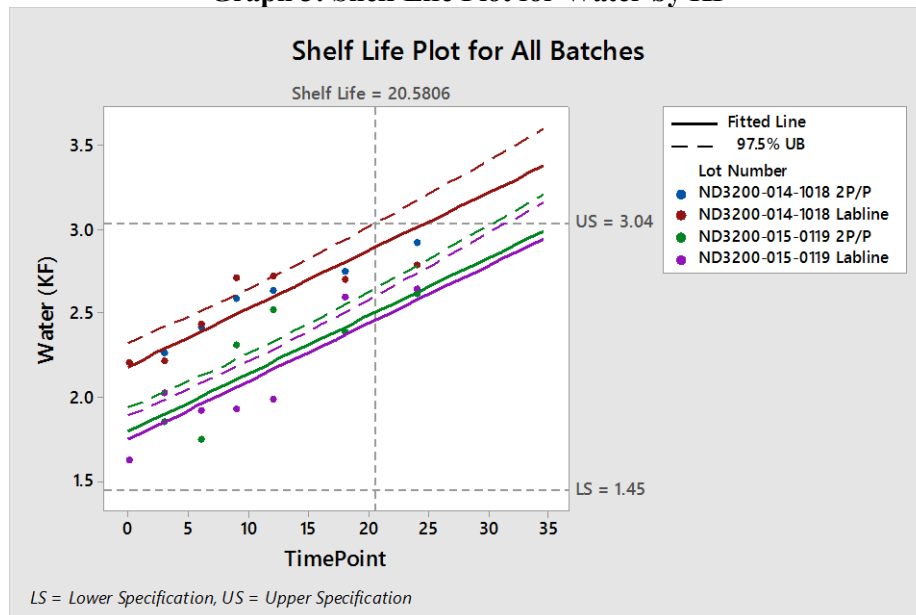
**Graph 2: Shelf Life Plot for Loss on Drying**

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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**7. STATEMENT OF COMMITMENT:**

- BioSpectra is responsible for the following regarding Stability Data in this report:
  - 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. 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.
  - 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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