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SODIUM DECANOATE LONG TERM STABILITY REPORT: 2021 VALIDATION LOTS

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1. OVERVIEW:

The purpose of this report is to analyze and conclude on the data obtained from the long-term stability study of Sodium Decanoate. Testing intervals are designated by T_n, where n = 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 Long-Term Stability analysis will assess the stability of Sodium Decanoate validation lots NDEC-0121-0133-PV, NDEC-0121-00001-PV, and NDEC-0121-00002-PV that completed thirty-six (36) months of long-term stability in April 2024 for lot NDEC-0121-0133-PV and June 2024 for lots NDEC-0121-00001-PV and NDEC-0121-00002-PV. This study includes the following analyses:

TABLE 1: SODIUM DECANOATE STABILITY SPECIFICATIONS

Analysis	Specification
Appearance	White to Off-White Powder
Assay (Dried Basis)	97.0 - 103.0%
Identification (IR)	Passes Test
Loss on Drying	≤3.0%
Single Impurities (GC)	<1.0%
Solubility in Water	Passes Test
Water (KF)	1.5 - 3.0%

Results from all analyses are summarized in Table 5 through Table 10. The data was analyzed utilizing a shelf-life plot, which determines the point in time at which the slope would exceed the acceptance criteria. As long as the slope has a statistically significant difference from zero using a 95% confidence limit, an estimated time in months can be established at which the acceptance criteria will no longer be met, i.e. the shelf life. This allows BioSpectra to ensure that the product is stable over the time period in which it is part of the stability program. All quantitative data was analyzed using these methods.

The stability program is designed to analyze for the stability indicating analyses established for a product in accordance with the Stability Testing Program BSI-SOP-0136. The specifications for the stability indicating analyses are established in accordance with the Stability Indication Protocol BSI-SOP-0289 when a new product is manufactured. The study is used to trend the data to determine if there is any significant change over the course of the study to establish the shelf life of the product. This study will be used to establish shelf life for all product codes of Sodium Decanoate. The following product codes are commercially available:

- NDEC-3201
- NDEC-3220
- NDEC-3320

2. REFERENCES:

2.1. BSI-LST-0160, Sodium Decanoate Stability Data Card
2.2. BSI-PRL-0200, Stability Indicating Protocol: Sodium Decanoate Bio Excipient Grade
2.3. BSI-RPT-0353, Stability Indicating Report: Sodium Decanoate Bio Excipient Grade
2.4. BSI-SOP-0136, Stability Testing Program
2.5. BSI-SOP-0146, Stability Inventory

2.6. BSI-SOP-0289, Stability Indication Protocol
2.7. Current USP
2.8. ICH Q1E

3. SAMPLE DESIGNATION:

3.1. Samples initially placed on the stability program consisted of three validation lots of Sodium Decanoate. Stability samples from these lots were put into Poly/Poly and Labline packaging configurations. The samples were packaged in accordance with the Stability Inventory SOP. Reference Table 1 for packaging configuration and description. The type of packaging utilized in this stability study was based on BioSpectra packaging offered to the customer.

TABLE 2: PACKAGING DETAILS

Packaging Configuration	Packaging Description
Poly/Poly (P/P)	Samples are individually placed into small polyethylene bags and are sealed with a zip tie. All individual bags are then placed into a poly pail and sealed.
Labline (HDPE Bottle)	Samples are packaged into a HDPE Lab Screw-Top Bottle.

4. STORAGE:

4.1. The Packaging and Storage requirements for Sodium Decanoate are to be in a tightly closed container at 2 to 8°C, and stored in a dry, well-ventilated area away from incompatible substances. For this study, Sodium Decanoate samples were stored in the refrigeration units A01RC02, A01RC04, and A01RC01 at the Bangor, PA facility. Storage conditions have been continuously measured and recorded utilizing Tempmate data loggers with regulated conditions for temperature (2 - 8°C). Section 5 will include any excursions from these conditions not explained by entrances into the refrigeration unit.

4.2. For NDEC-0121-0133-PV: These samples were located in refrigeration unit A01RC02 from April 2021 to May 2021. 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. These samples were stored in refrigeration unit, A01RC04, for the time period of May 2021 to September 2023. In September 2023, the samples were moved to refrigeration unit, A01RC01, due to temporary operating instruction, BTOI23-143, which was a result of BDI23-234. These samples were stored in refrigeration unit A01RC01 for the time period of September 2023 – April 2024, which covers up to the T_{36} (36 month) timepoint for this sample set. All remaining samples will remain in this storage condition until the final pull at T_{60}, which is scheduled for April 2026. See table 3 for storage conditions reported for NDEC-0121-0133-PV.

TABLE 3: NDEC-0121-0133-PV STORAGE CONDITIONS

Condition	Specification	Value
April 2021 – May 2021 (A01RC02)		
Minimum Temperature	2 - 8°C	3.3
Maximum Temperature		25.7
Average Temperature		8.8
Mean Kinetic Temperature	Monitor	11.2
May 2021 – September 2023 (A01RC04)		
Minimum Temperature	2 - 8°C	-5.6
Maximum Temperature		48.3
Average Temperature		6.4
Mean Kinetic Temperature	Monitor	7.6
September 2023 – April 2024 (A01RC01)		
Minimum Temperature	2 - 8°C	3.3
Maximum Temperature		26.4
Average Temperature		5.9
Mean Kinetic Temperature	Monitor	5.9

4.3. For NDEC-0121-00001-PV and NDEC-0121-00002-PV: These samples were stored in refrigeration unit A01RC04 for the time period of June 2021 until September 2023. In September 2023, the samples were moved to refrigeration unit, A01RC01, due to temporary operating instruction, BTOI23-143, which was a result of BDI23-234. These samples were stored in refrigeration unit A01RC01 for the time period of September 2023 – July 2024, which covers up to the T_{36} (36 month) timepoint for these sample sets. All remaining samples will remain in this storage condition until the final pull at T_{60}, which is scheduled for July 2026. See Table 4 for storage conditions reported for NDEC-0121-00001-PV and NDEC-0121-00002-PV.

TABLE 4: NDEC-0121-00001-PV & NDEC-0121-00002-PV STORAGE CONDITIONS

Condition	Specification	Value
May 2021 – September 2023 (A01RC04)		
Minimum Temperature	2 - 8°C	-5.6
Maximum Temperature		48.3
Average Temperature		6.4
Mean Kinetic Temperature	Monitor	7.6
September 2023 – July 2024 (A01RC01)		
Minimum Temperature	2 - 8°C	3.3
Maximum Temperature		26.4
Average Temperature		5.9
Mean Kinetic Temperature	Monitor	5.9

5. INVESTIGATIONS:

5.1. **BCL24-110**: NDEC-0121-00001-PV and NDEC-0121-00002-PV P/P and Labline T=36 samples were stored improperly after pulling for testing. The samples were discarded and new pulls of T=Extra samples were used to replace the T=36 samples.

5.2. **BDI21-142**: NDEC-0121-00001-PV and NDEC-0121-00002-PV were not placed on stability until June 2021 when the samples were received in April 2021 and May 2021, respectively, due to a storage in stability components to package and place the samples on stability.

5.3. **BDI21-204**: A planned discrepancy to test NDEC-0121-00001-PV T=3 P/P and Labline as well as NDEC-0121-00002-PV T=3 P/P and Labline after the allotted 10 business days for GC impurities testing due to insufficient scheduling of the instrument. The samples were tested on 9/15/21.

5.4. **BDI21-259**: This discrepancy investigation documents several temperature excursions between the dates of 02/26/21 and 06/18/21 for refrigeration unit A01RC02. This investigation resulted in moving the stability samples from refrigeration unit A01RC02 to refrigeration unit A01RC04. This move was documented in Temporary Operating Instruction BTOI21-84. It was determined that there was no impact on the samples.

5.5. **BDI22-86**: Temperature excursions were recorded in A01RC01 on 2/14/22 and 11/16/21. The excursion found on 2/14/22 was attributed to an entry into the trailer that was not recorded in the log book. The excursion found on 11/16/21 was attributed to the logger not being acclimated to the cold storage container for the first reading. It was determined that there was no impact to any samples.

5.6. **BDI22-192**: This investigation was issued due to incorrect date recordings by Tempmate. It was determined as device error of the Tempmate S1 loggers as the internal date settings were incorrect. Tempmate was contacted and there is no impact to any samples.

5.7. **BDI22-193**: This discrepancy covers missing temperature and humidity assessments for refrigerated storage container A01RC04 for the time period of 02/26/21 to 10/28/21. Tempmate S1 data loggers were retrieved and the data was collected, however the formal assessment was never submitted to and approved by Quality Assurance. It was determined that there was no impact on the samples stored in the unit during this time period.

5.8. **BDI23-09**: This discrepancy covers one of the temperature data loggers being missing for the time period of 06/23/22 to 09/14/22, and not being able to retrieve data for that area of Cold Storage Container A01RC04. There were also out of specification (OOS) results obtained that could not be explained by container entrances. The root cause was determined to be the style of temperature data logger being used is easily knocked down and could possibly be removed on pallets stored in the unit. The OOS results were determined to be from entry into the unit that was not recorded in the log book. It was determined that there was no impact on samples stored in the unit.

5.9. **BDI23-17**: This discrepancy covers out of specification (OOS) temperatures for Cold Storage Container A01RC04 for the period of 03/07/22 to 06/23/22 that are not explained by container entrances. The root cause was determined to be entry into this storage unit that was not logged into the book, as the OOS results were recorded on the temperature data loggers closest to the door. It was determined that there was no impact on samples stored in this unit.

5.10. **BDI23-18**: This discrepancy covers out of specification (OOS) results for Cold Storage Container A01RC04 for the period of 09/14/22 to 12/21/22 that are not explained by container entrances. The root cause was determined to be entry into this storage unit that was not logged into the book. It was determined that there was no impact on samples stored in this unit.

5.11. **BDI23-30**: Low temperature excursions were recorded for A01RC04 that was not due to documented entry into the storage unit. During the investigation it was determined that entry into the cold storage unit was not logged into the log book. It was determined that there was no impact to any samples since the excursions were only for a short period.

5.12. **BDI23-90**: This discrepancy covers Out of Specification (OOS) results for refrigeration unit A01RC04 that are not explained by entrances into the container. The OOS results were recorded only on the two Tempmate data loggers closest to the entry point, while the loggers located in the rear of the container remained within specification. This indicated that there was an entrance that was unaccounted for. It was determined that there was no impact on samples stored in this unit.

5.13. **BDI23-125**: This discrepancy covers a calculation error for samples NDEC-0121-0133-PV T=18 P/P and Labline. The standard data was not processed and saved correctly, and therefor did not apply the appropriate Reporting Threshold to the sample data. This only had a minor effect on the final calculated result, not enough to push the samples from in specification to out of specification, but it did have an effect on the final reportable value for the Labline packaging configuration. The result changed from 0.14%, which is reported as 0.1%, to 0.15%, which is reported as 0.2%. The correction was captured in this investigation, and all digital and physical records were updated with the reprocessed data.

5.14. **BDI23-206**: Low temperature excursions were recorded for A01RC04 that was not due to documented entry into the storage unit. During the investigation it was determined that entry into the cold storage unit was not logged into the log book. It was determined that there was no impact to any samples since the excursions were only for a short period.

5.15. **BDI23-212**: This investigation covers high Out of Specification (OOS) temperatures that are not explained by container entrances that occurred in refrigerated storage container A01RC04. These temperatures were recorded in June and July of 2023. The investigation determined that the OOS temperatures were most likely due to entries into the container that were not properly documented in the logbook. It was determined that these excursions were for relatively short amounts of time, and that the average temperatures were maintained within specification, so there was no impact on samples stored in the unit at this time.

5.16. **BDI23-234**: The cold storage Trailer A01RC04 was observed to be 48.9°C on 8/28/23. It was determined that the cold storage unit compressor had failed. Review of the temperature data showed an increase in the temperature starting on 8/24/23. The stability samples were moved from A01RC04 to A01RC01 under BTOI23-143 on 9/8/23. Based on the 18-month stability pull data this excursion had no impact on the samples to date.

5.17. **BDI24-33**: This discrepancy covers out of specification (OOS) high temperatures for the period of 9/1/23 to 12/13/23 for Cold Storage Container A01RC01 that are not explained by container entrances. The root cause was determined to be entry into this storage unit that was not logged into the book. It was determined that there was no impact on samples stored in this unit.

5.18. **BDI24-50**: During the download and review of the Tempmate data loggers in A01RC01 for the period 12/13/23 to 3/28/24 high OOS temperatures that are not explained by container entries were recorded from 3/17/24 to 3/19/24. The root cause was due to a malfunctioning compressor. Based on the 24-month stability pull data this excursion had no impact on the samples to date.

5.19. **BDI24-56**: High out of specification OOS temperatures recorded by all four loggers for Cold Storage Container A01RC01 were recorded on 7/17/23, 7/26/23, and 8/24/23-8/28/23. Additionally, logger S/N S122122089-12 recorded high OOS temperatures on 7/14/23, 7/15/23, 7/28/23, 7/29/23 and 8/6/23. The main root cause was due to a malfunctioning compressor or chamber entrance. The stability of the 2-MEA samples was not impacted as the last time point met the specification requirements.

5.20. **BDI24-128:** The temperature monitors exceeded the 100 day download limit on 7/17/24 but was not changed until 8/12/24. As a result, the data between those two dates was not recorded. There were also a few out of specification temperature excursions that were likely due to the placement of a logger on the floor where airflow could have been obstructed or unlogged entries into the chamber. It was determined that there was no impact to any samples since the excursions were only for a short period.

5.21. **BDI24-169**: High temperature excursions were recorded for A01RC01 that was not due to documented entry into the storage unit. During the investigation it was determined that entry into the cold storage unit was not logged into the log book. The OOS from 11/4/24 to 11/9/24 was determined to be from a damaged exhaust fan motor. BWO24-692 and BWO24-698 were issued and there was no impact to any samples since the excursions were only for a short period.

5.22. **BLI24-18**: High out of specification OOS for KF Water for batch NDEC-0121-00002-PV P/P T= 36 months. The result obtained was 3.20%. Four out of the six of the retests did not meet the specification with the average of 3.14% obtained. A T=Extra sample was pulled to rule out sampling handling as a root cause for the OOS results and a passing result of 2.97% was obtained. The t=extra result will be reported as the official result for NDEC-0121-00002-PV P/P t=36.

6. LOT EVALUATION:

TABLE 5: RESULT OF LONG-TERM STABILITY ANALYSES FOR NDEC-0121-0133-PV P/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 (Dried Basis)	97.0 – 103.0%	101.09%	99.37%	100.01%	100.04%	99.46%	99.65%	99.80%	99.55%
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Loss on Drying	≤3.0%	2.5740%	2.4362%	2.3975%	2.6737%	2.4399%	2.5415%	2.6626%	2.5369%
Single Impurities (GC)	< 1.0%	0.12%	0.14%	0.13%	0.09%	0.07%	0.18%	0.29%	0.15%
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Karl Fischer Water (KF)	1.5 – 3.0%	2.57%	2.49%	2.50%	2.32%	2.46%	2.50%	2.85%	2.97%
Additional Information Report Only									
Quantitative Impurities[1]	Sodium Octanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.03%	< 0.1%
	Sodium Nonanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.03%	< 0.1%
	Unspecified[2]	0.12%	0.14%	0.13%	0.09%	0.07%	0.18%	0.23%	0.15%
	Total Impurity	0.12%	0.14%	0.13%	0.09%	0.07%	0.18%	0.29%	0.15%

[1]Quantitative Impurities (GC) are included in the table for information reporting purposes, but there is no set specification for these impurities for the stability program.
[2]Identified as 2-Decanoic Acid

REMAINING TESTING INTERVAL PULL DATES

- **T=48; Scheduled to be pulled 04/19/25**
- **T=60; Scheduled to be pulled 04/19/26**

TABLE 6: RESULT OF LONG-TERM STABILITY ANALYSES FOR NDEC-0121-0133-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 (Dried Basis)	97.0 – 103.0%	101.09%	98.77%	99.52%	100.04%	99.43%	99.73%	99.82%	99.79%
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Loss on Drying	≤3.0%	2.5740%	2.2668%	2.3729%	2.5326%	2.4382%	2.6797%	2.5588%	2.5511%
Single Impurities (GC)	< 1.0%	0.12%	0.15%	0.12%	0.09%	0.08%	0.15%	0.31%	0.13%
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Karl Fischer Water (KF)	1.5 – 3.0%	2.57%	2.50%	2.42%	2.33%	2.48%	2.58%	2.58%	2.85%
Additional Information Report Only									
Quantitative Impurities[1]	Sodium Octanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.03%	< 0.1%
	Sodium Nonanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.03%	< 0.1%
	Unspecified[2]	0.12%	0.15%	0.12%	0.09%	0.08%	0.15%	0.24%	0.11%
	Total Impurity	0.12%	0.15%	0.12%	0.09%	0.08%	0.15%	0.31%	0.13%

[1]Quantitative Impurities (GC) were also implemented to identify the impurities in these samples over time, but there is no set specification for these impurities for the stability program.
[2]Identified as 2-Decanoic Acid

REMAINING TESTING INTERVAL PULL DATES

- **T=48; Scheduled to be pulled 04/19/25**
- **T=60; Scheduled to be pulled 04/19/26**

TABLE 7: RESULT OF LONG-TERM STABILITY ANALYSES FOR NDEC-0121-00001-PV P/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 powder	White to off-white powder	White to off-white powder	White to off-white powder	White to off-white powder	White powder
Assay (Dried Basis)	97.0 – 103.0%	99.35%	101.53%	99.83%	99.90%	99.94%	99.51%	99.57%	100.01%
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Loss on Drying	≤3.0%	2.2765%	2.3347%	2.3720%	2.3138%	2.3684%	2.4283%	2.6625%	2.5155%
Single Impurities (GC)	< 1.0%	0.12%	0.11%	0.08%	0.09%	0.06%	0.06%	0.25%	0.14%
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Karl Fischer Water (KF)	1.5 – 3.0%	2.33%	2.52%	2.40%	2.38%	2.73%	2.47%	2.65%	2.64%
Additional Information Report Only									
Quantitative Impurities[1]	Sodium Octanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.02%	< 0.1%
	Sodium Nonanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.03%	0.02%
	Unspecified[2]	0.12%	0.11%	0.08%	0.07%	0.06%	0.06%	0.20%	0.10%
	Total Impurity	0.12%	0.11%	0.08%	0.09%	0.06%	0.06%	0.25%	0.14%

[1]Quantitative Impurities (GC) were also implemented to identify the impurities in these samples over time, but there is no set specification for these impurities for the stability program.
[2]Identified as 2-Decanoic Acid

REMAINING TESTING INTERVAL PULL DATES

- **T=48; Scheduled to be pulled 06/03/25**
- **T=60; Scheduled to be pulled 06/03/26**

TABLE 8: RESULT OF LONG-TERM STABILITY ANALYSES FOR NDEC-0121-00001-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 powder	White to off-white powder	White to off-white powder	White to off-white powder	White to off-white powder	White powder
Assay (Dried Basis)	97.0 – 103.0%	99.35%	101.79%	99.80%	100.07%	99.83%	99.60%	99.48%	99.66%
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Loss on Drying	≤3.0%	2.2765%	2.3706%	2.5371%	2.3669%	2.4299%	2.5894%	2.5320%	2.6046%
Single Impurities (GC)	< 1.0%	0.12%	0.12%	0.10%	0.09%	0.06%	0.08%	0.26%	0.15%
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Karl Fischer Water (KF)	1.5 – 3.0%	2.33%	2.45%	2.52%	2.32%	2.65%	2.54%	2.69%	2.68%
Additional Information Report Only									
Quantitative Impurities[1]	Sodium Octanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.02%	< 0.1%
	Sodium Nonanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.03%	0.02%
	Unspecified[2]	0.12%	0.12%	0.10%	0.09%	0.06%	0.07%	0.21%	0.10%
	Total Impurity	0.12%	0.12%	0.10%	0.09%	0.06%	0.08%	0.26%	0.15%

[1]Quantitative Impurities (GC) were also implemented to identify the impurities in these samples over time, but there is no set specification for these impurities for the stability program.
[2]Identified as 2-Decanoic Acid

REMAINING TESTING INTERVAL PULL DATES

- **T=48; Scheduled to be pulled 06/03/25**
- **T=60; Scheduled to be pulled 06/03/26**

TABLE 9: RESULT OF LONG-TERM STABILITY ANALYSES FOR NDEC-0121-00002-PV P/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 powder	White to off-white powder	White to off-white powder	White to off-white powder	White to off-white powder	White powder
Assay (Dried Basis)	97.0 – 103.0%	99.75%	101.83%	99.78%	100.25%	99.87%	99.79%	99.68%	99.55%
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Loss on Drying	≤3.0%	2.2223%	2.3423%	2.3882%	2.3678%	2.4334%	2.4912%	2.5592%	2.8286%
Single Impurities (GC)	< 1.0%	0.13%	0.11%	0.09%	0.08%	0.07%	0.05%	0.26%	0.17%
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Karl Fischer Water (KF)	1.5 – 3.0%	2.35%	2.53%	2.78%	2.51%	2.74%	2.52%	2.76%	2.97%
Additional Information Report Only									
Quantitative Impurities[1]	Sodium Octanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.02%	0.01%
	Sodium Nonanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.02%	0.02%
	Unspecified[2]	0.13%	0.11%	0.09%	0.07%	0.07%	0.05%	0.21%	0.11%
	Total Impurity	0.13%	0.11%	0.09%	0.08%	0.07%	0.05%	0.26%	0.17%

[1]Quantitative Impurities (GC) were also implemented to identify the impurities in these samples over time, but there is no set specification for these impurities for the stability program.
[2]Identified as 2-Decanoic Acid

REMAINING TESTING INTERVAL PULL DATES

- **T=48; Scheduled to be pulled 06/03/25**
- **T=60; Scheduled to be pulled 06/03/26**

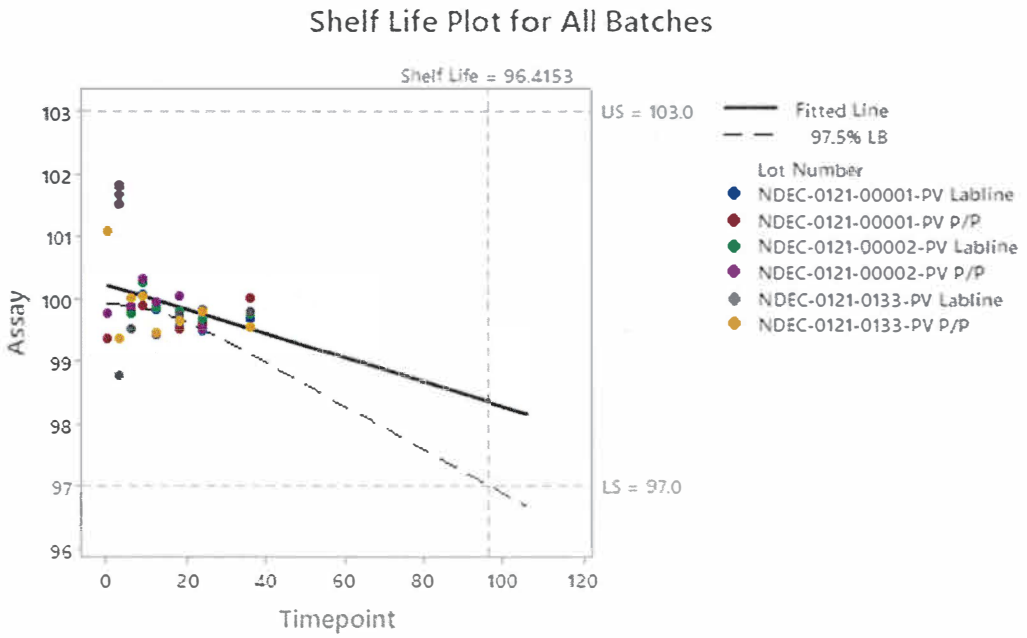
TABLE 10: RESULT OF LONG-TERM STABILITY ANALYSES FOR NDEC-0121-00002-PV LABLINE

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 powder	White to off-white powder	White to off-white powder	White to off-white powder	White to off-white powder	White powder
Assay (Dried Basis)	97.0 – 103.0%	99.75%	101.67%	99.88%	100.31%	99.96%	100.03%	99.52%	99.75%
Identification (IR)	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Loss on Drying	≤3.0%	2.2223%	2.2377%	2.3800%	2.3483%	2.4917%	2.4393%	2.3435%	2.4683%
Single Impurities (GC)	< 1.0%	0.13%	0.12%	0.10%	0.14%	0.07%	0.08%	0.25%	0.15%
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
Karl Fischer Water (KF)	1.5 – 3.0%	2.35%	2.65%	2.81%	2.41%	2.56%	2.46%	2.64%	2.78%
Additional Information Report Only									
Quantitative Impurities[1]	Sodium Octanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.02%	< 0.1%
	Sodium Nonanoate	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	< 0.1%	0.02%	0.01%
	Unspecified[2]	0.13%	0.12%	0.10%	0.08%	0.07%	0.07%	0.21%	0.10%
	Total Impurity	0.13%	0.12%	0.10%	0.14%	0.07%	0.08%	0.25%	0.15%

[1]Quantitative Impurities (GC) were also implemented to identify the impurities in these samples over time, but there is no set specification for these impurities for the stability program.
[2]Identified as 2-Decanoic Acid

REMAINING TESTING INTERVAL PULL DATES

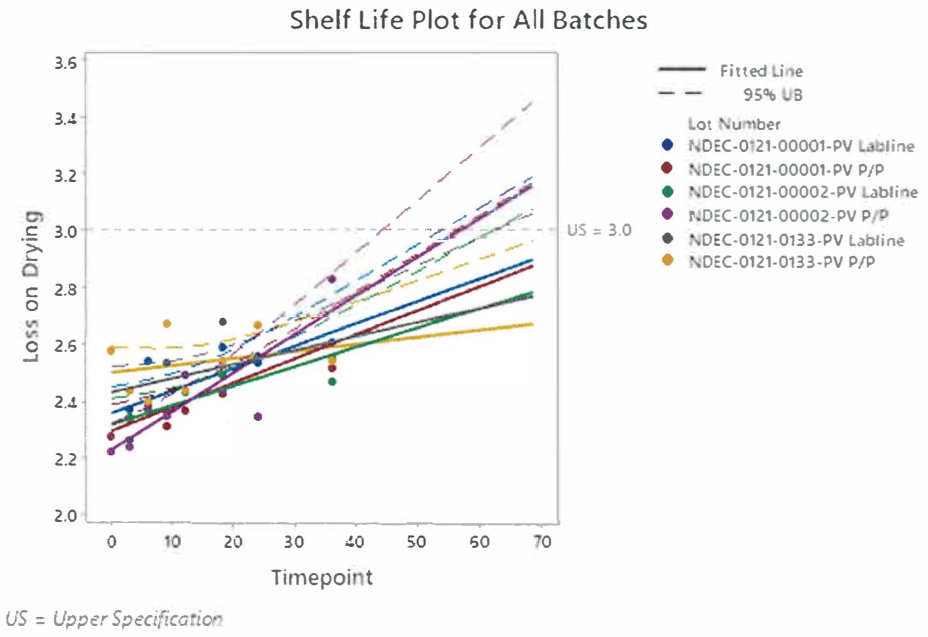
- **T=48; Scheduled to be pulled 06/03/25**
- **T=60; Scheduled to be pulled 06/03/26**



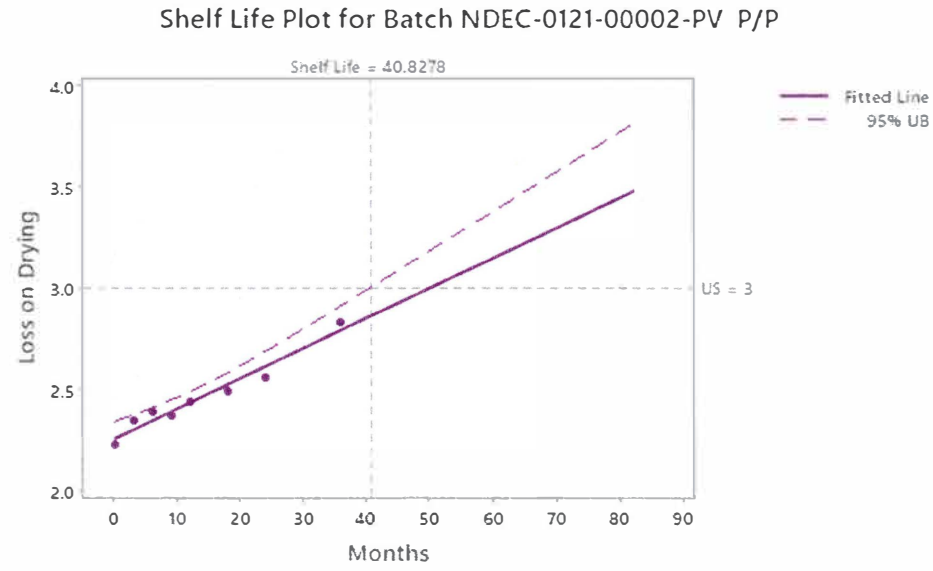
LS = Lower Specification, US = Upper Specification
Equation for fitted line: Assay = 100 - 0.0193 Timepoint

GRAPH 1: ASSAY

The predicted shelf-life for Assay was determined to be 96.4153 months at the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.



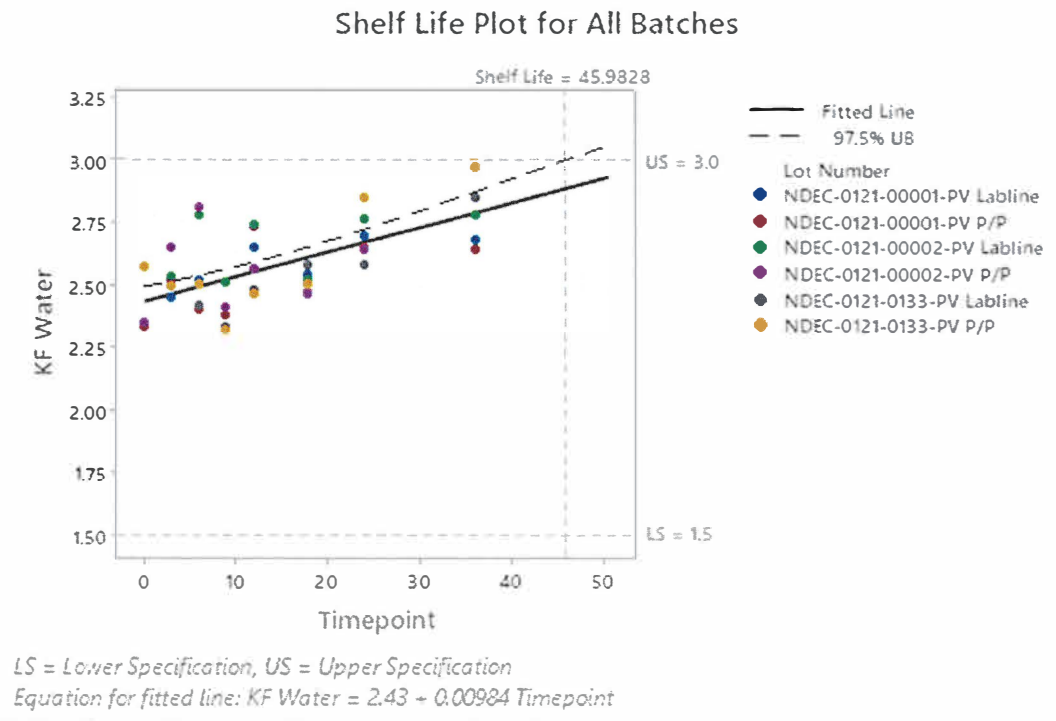
US = Upper Specification



US = Upper Specification
Equation for fitted line: Loss on Drying = 2.25 + 0.0148 Months

GRAPH 2: LOSS ON DRYING

The predicted shelf-life for Loss on Drying was determined to be 40.8278 months at the T=36-month time interval for NDEC-0121-00002-PV P/P. 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 was determined to be 45.9828 months at the T=36-month time interval. Results will continue to be monitored. There is no impact to the product or currently assigned retest period of this material.

7. CONCLUSION:

All data met the specifications set forth in the Stability Testing Program. In accordance with ICH Q1E, the retest date may be proposed for up to 1.5x, where x is the period covered by long-term stability data, but should be no more than 6 months beyond for refrigerated conditions. Long term stability data displayed in this report up to 36 months of testing for three lots of Sodium Decanoate manufactured at BioSpectra in the Bangor, PA facility, along with the predicted shelf-life plots, supports a retest date of 40 months and will continued to be monitored through the remainder of the timepoints. The current retest date of 24 months will remain and an extended retest date of 36 months may be assigned upon request.

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.

8.1.2. 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.

8.1.3. 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.

8.1.4. In the event that any out of specification results are confirmed, all authorized users of the material will be notified.