BIOSPECTRA
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5M SODIUM CHLORIDE 2020 VALIDATION BATCHES LONG TERM STABILITY REPORT

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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 5M Sodium Chloride. Testing intervals are designated by T_n, where *n* designates 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 three validation lots, NC3100-001-0620-PV, NC3100-002-0820-PV and NC3100-003-0820-PV of 5M Sodium Chloride, that completed thirty-six months of long-term stability in August 2023. The study included the analyses listed in Table 1. Results from all analyses are summarized in Tables 4 through 6.

Table 1: Stability Specifications

Analysis	Specifications
Appearance and Color	Clear, Colorless Solution
Assay (Molarity)	4.9 – 5.1M
Endotoxin	<2.5 EU/mL
Identification <Chloride>	Meets Requirements
Identification <Sodium>	Meets Requirements
Microbial Analysis	TAMC ≤50 CFU/g
	TYMC ≤150 CFU/g

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 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 5M Sodium Chloride. The following product codes are commercially available.

- NACL-3150

2. REFERENCES:

2.1. BSI-MEM-0852, Sodium Chloride 5M Stability Indicating Justification
2.2. BSI-SOP-0136, Stability Testing Program
2.3. BSI-SOP-0146, Stability Inventory
2.4. Current USP
2.5. ICH Q1E

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3. SAMPLE DESIGNATION:

3.1. Samples placed on the stability program consisted of three lots of 5M Sodium Chloride. Stability samples from these lots were put into the Sample bags packaging configuration. The samples were packaged in accordance with Stability Inventory, BSI-SOP-0146. Reference Table 2 for packaging configuration and description. The type of packaging utilized in this stability study was based on BioSpectra's packaging offered to the customer.

Table 2: Packaging Details

Packaging Configuration	Packaging Description
Sample Bags	1 L Polyethylene bio-containers pre-made one time use bags designed specifically for fluid handling

4. STORAGE:

4.1. The Packaging and Storage requirements for 5M Sodium Chloride are to be stored at room temperature. For this study, the samples were stored in the Long-Term Stability Chamber at the Bangor, PA facility from June 2020 until the last sample time point in August 2023. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature (25°C ±2), mean kinetic temperature (monitor) and relative humidity (60% ±5). The storage conditions for the period of this study are detailed in Table 3.

Table 3: Storage conditions

Condition	Specification	Value
Minimum Temperature	25°C ± 2°C	22.63°C
Maximum Temperature		27.80°C
Average Temperature		25.46°C
Mean Kinetic Temperature	Monitor	25.46°C
Minimum Humidity	60% ± 5% RH	31.1%
Maximum Humidity		72.4%
Average Humidity		61.4%

4.2. 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 resulted in an investigation.

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5. INVESTIGATIONS:

5.1. **BDI22-61**: During the download of the long-term temperature and humidity data it was noticed that there was missing data for the month of February 2022. This was due to a malfunction of the Madgetech data logger. There was no impact on the stability samples as the analog chart recorder showed no deviations.

5.2. **BDI22-138**: During the download of the long-term temperature and humidity data it was noticed that there was out of specification humidity readings. This was due to a valve to the humidifier being closed. There is no impact on the stability samples as this excursion was brief, lasting less than 5 hours.

5.3. **BDI22-143**: Missing data points were identified during the download of the long-term stability data for the month of November 2021. This was caused from the depletion of the batteries in the recording device. There was no impact on the stability samples as the analog chart recorder showed no deviations.

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6. LOT EVALUATION:

Table 4: NC3100-001-0620-PV Sample Bag

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}
Appearance	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution
Assay	4.9-5.1 M	5.02 M	5.04 M	5.06 M	5.10 M	5.05 M	5.03 M	5.08 M	5.08 M
Endotoxin	<2.5 EU/mL	<0.259 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL
Sodium	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement
Chloride	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement
Microbial Content	TAMC ≤50 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g
	TYMC ≤150 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g

Table 5: NC3100-002-0820-PV Sample Bag

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}
Appearance	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution
Assay	4.9-5.1 M	5.02 M	5.01 M	4.96 M	4.99 M	5.01 M	5.02 M	5.08 M	5.03 M
Endotoxin	<2.5 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL
Sodium	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement
Chloride	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement
Microbial Content	TAMC ≤50 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g
	TYMC ≤150 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g

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Table 6: NC3100-003-0820-PV Sample Bag

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}
Appearance	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution	Clear, Colorless Solution
Assay	4.9-5.1 M	5.02 M	5.10 M	4.95 M	5.04 M	5.09 M	5.10 M	5.12 M[1]	5.08 M
Endotoxin	<2.5 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL	<0.294 EU/mL
Sodium	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement
Chloride	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement	Meets Requirement
Microbial Content	TAMC ≤50 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g
	TYMC ≤150 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g

[1]Reported Result is 5.1M and meets specification.

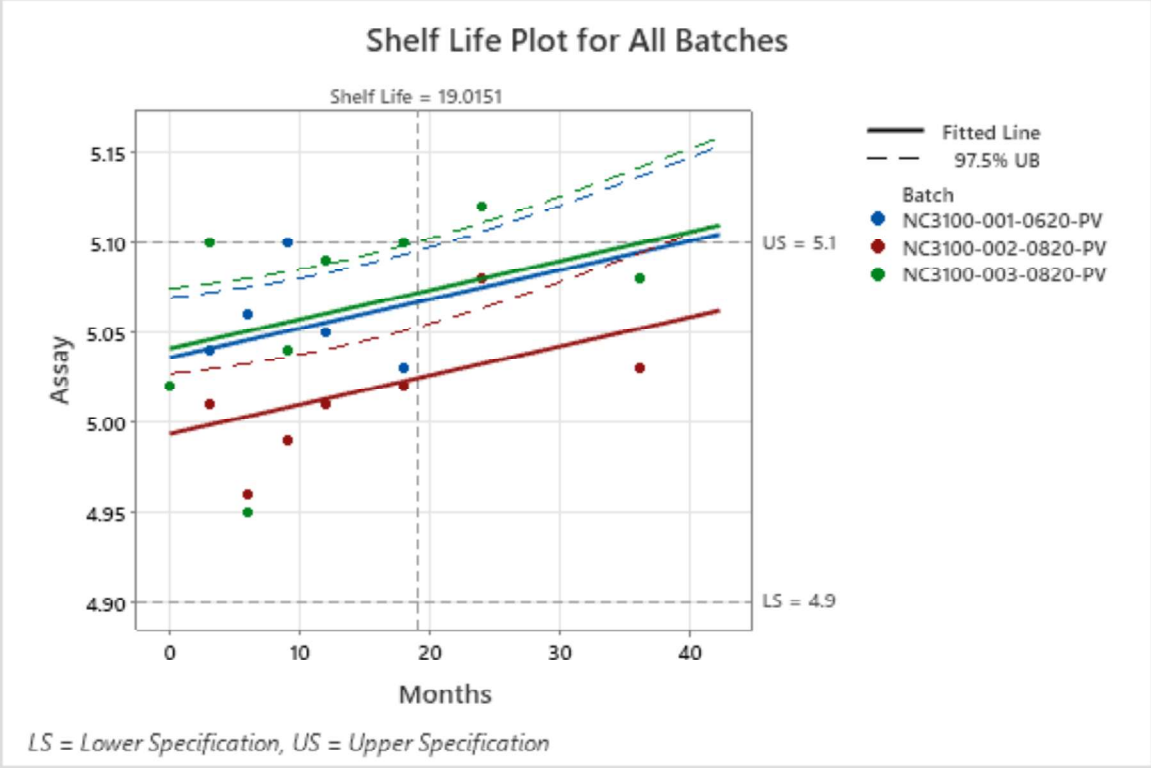

Figure 1: Graph Assay

The predicted shelf-life for Assay was determined to be 19.0151 months. The shelf-life is defined as the time period in which you may be 95% confident that at least 50% of the response is within the required limits of specifications. All data up to the 36-month time point has met the required specification. There is no risk to a shelf-life of 36 months as the material is currently meeting the required specification.

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7. CONCLUSION:

In regards to the long-term Stability Study for 5M Sodium Chloride 2020 stability, all data met the specifications set forth in the Stability Testing Program for lot stored at the recommended long-term condition up to the 36-month time point. In accordance with ICH Q1E, 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. Long-Term stability data displayed in this report supports the current expiration date of 24 months for 5M Sodium Chloride manufactured at BioSpectra in the Bangor, PA facility. Due to the completion of 5M Sodium Chloride 36-month stability study, a 24-month retest date will be assigned and a 36-month expiration date 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.

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