BIOSPECTRA
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# 10N SODIUM HYDROXIDE 2023 REAL-TIME STABILITY REPORT

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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 10N Sodium Hydroxide. 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 real time stability analysis will assess the stability of one lot of 10N Sodium Hydroxide, NAHY-0123-00001, that completed eighteen (18) months of real-time stability in July 2024. The study included the following analyses: Appearance and Color, Identification (Sodium), Normality, and Sodium Carbonate. Results from all analyses are summarized in Table 2. 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 10N Sodium Hydroxide. The following product codes are commercially available.

- NAHY-4122
- NAHY-4150

## 2. REFERENCES:

2.1. BSI-SOP-0136, Stability Testing Program
2.2. BSI-SOP-0146, Stability Inventory
2.3. BSI-SOP-0289, Stability Indication Protocol
2.4. Current USP
2.5. ICH Q1E

## 3. SAMPLE DESIGNATION:

3.1. Samples placed on the stability program consisted of one lot of 10N Sodium Hydroxide. Stability samples from these lots were put into the 250 mL HDPE Bottle packaging configuration. The samples were packaged in accordance with the Stability Inventory SOP, BSI-SOP-0146. 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 1: PACKAGING DETAILS**

| Packaging Configuration | Packaging Description |
|---|---|
| HDPE Bottle | Samples are packaged into 250 mL HDPE Lab Screw-Top Bottle |

## 4. STORAGE:

4.1. The packaging and storage requirements for 10N Sodium Hydroxide are to be stored in a cool, well-ventilated, and dry area above 15.5°C in accordance with the SDS. For this study, the samples were stored in the Real Time Stability Chamber, H03SC01, at the Bangor, PA facility from January 2023 until the last sample time point in July 2024. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature (25°C ±2°C), mean kinetic temperature (monitored) and relative humidity (60% ±5%). For this period, the maximum temperature recorded was 25.73°C, the minimum temperature was 24.84°C, the average temperature was 25.42°C, and the average Mean Kinetic Temperature was 25.42°C. The maximum relative humidity recorded was 80.5%, the minimum relative humidity was 43.6%, and the average relative humidity was 61.3%. 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.

## 5. INVESTIGATIONS:

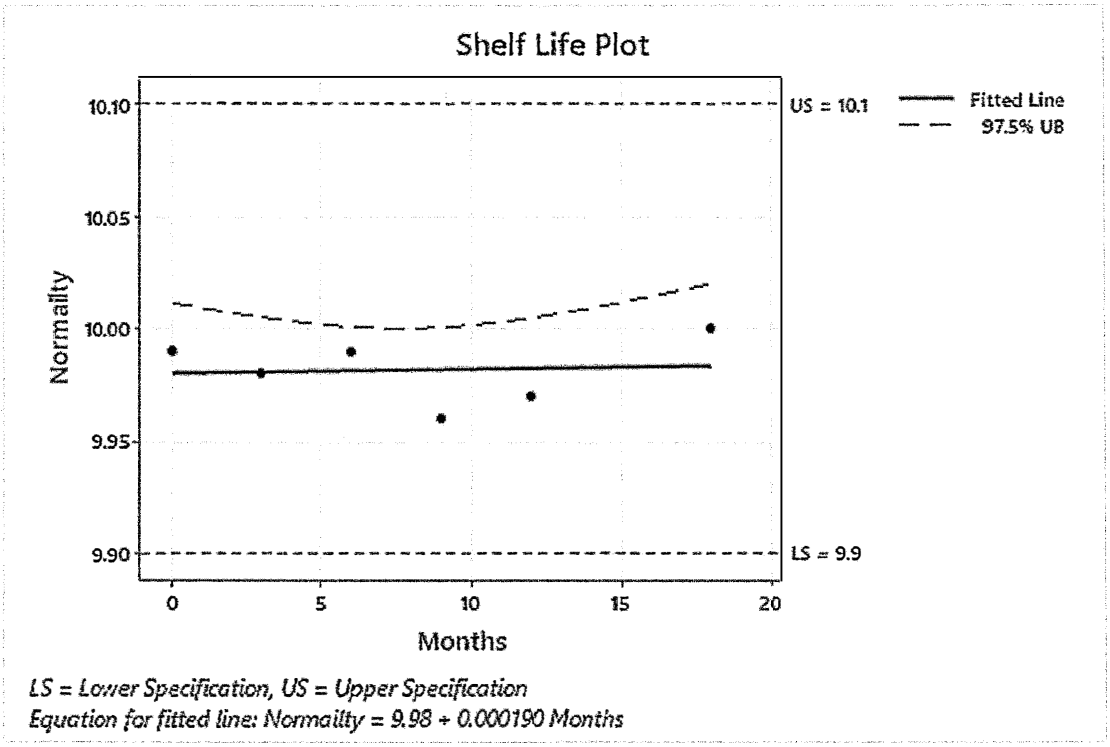
5.1. BDI24-13: This discrepancy documents out of range humidity observed for the Real Time Stability Chamber H03SC01 caused by improper work order completion to prevent water leaking from the stability chamber. On 1/15/24 while conducting a maintenance walkthrough of the Bangor, PA facility, water was observed on the floor of room H03RM01. The issue was found to be a faulty pump and later repaired. There was no impact to the current list of materials in the stability chamber.

## 6. LOT EVALUATION:

**TABLE 2: NAHY-0123-00001 HDPE BOTTLE**

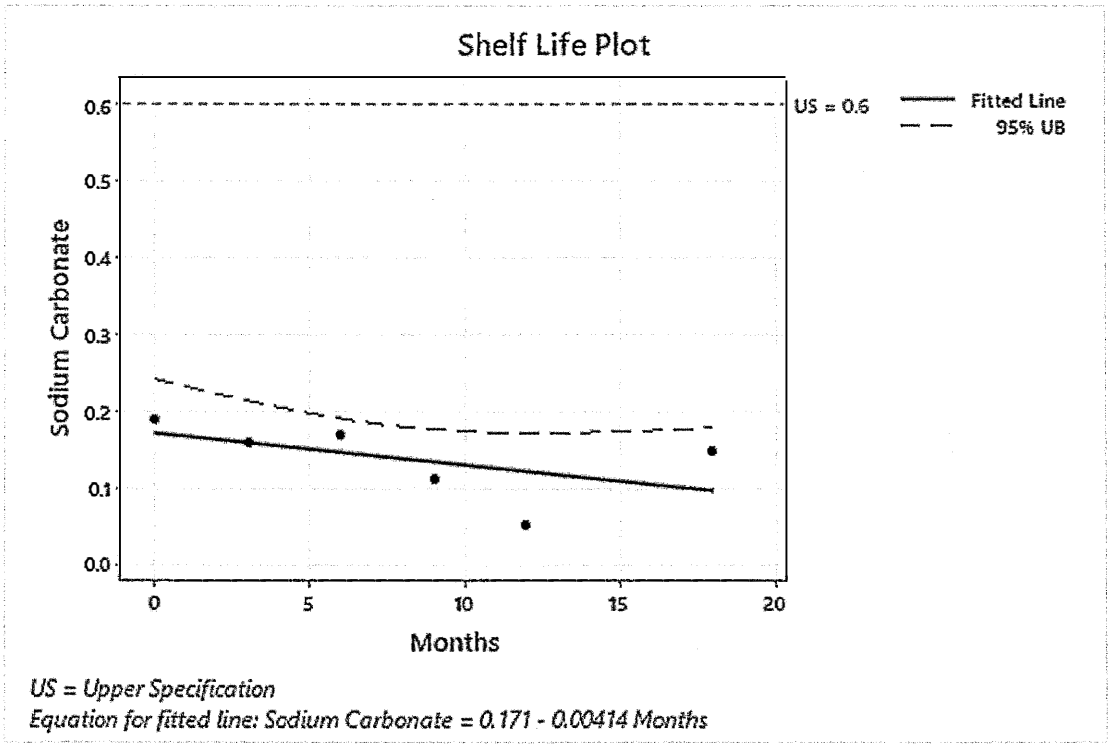
| Analysis | Specification | $T_0$ | $T_3$ | $T_6$ | $T_9$ | $T_{12}$ | $T_{18}$ |
|---|---|---|---|---|---|---|---|
| Appearance and Color | Clear/Colorless Liquid | Clear/ Colorless Liquid | Clear/ Colorless Liquid | Clear/ Colorless Liquid | Clear/ Colorless Liquid | Clear/ Colorless Liquid | Clear/ Colorless Liquid |
| Identification (Sodium) | Passes Test for Sodium | Passes Test for Sodium | Passes Test for Sodium | Passes Test for Sodium | Passes Test for Sodium | Passes Test for Sodium | Passes Test for Sodium |
| Normality | 9.9 – 10.1 N | 9.99 N | 9.98 N | 9.99 N | 9.96 N | 9.97 N | 10.00 N |
| Sodium Carbonate | ≤ 0.6% | 0.19% | 0.16% | 0.17% | 0.11% | 0.05% | 0.1480% |

- **REMAINING TESTING INTERVAL PULL DATES**
  - T = 24; Scheduled for January 10, 2025
  - T = 36; Scheduled for January 10, 2026
  - T = 48; Scheduled for January 10, 2027
  - T = 60; Scheduled for January 10, 2028




**GRAPH 1: NORMALITY**

No shelf life was able to be determined for Normality using the statistical analysis for shelf life plot, 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 or expiration of this material as represented by this data up to 18-months.




**GRAPH 2: SODIUM CARBONATE**

No shelf life was able to be determined for Sodium Carbonate using the statistical analysis for shelf life plot, 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 or expiration of this material as represented by this data up to 18 months.

## 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 2x, where x is the period covered by long-term stability data, but should be no more than 12 months beyond. Real-Time Stability Data displayed in this report, along with the predicted shelf-life plots, supports the currently assigned retest and expiration dates of 10N Sodium Hydroxide manufactured at BioSpectra in the Bangor, PA facility. The results continue to support the already established retest date of 24 months and expiration date of 36 months.

## 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.