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POTASSIUM BROMIDE 2023 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 Potassium Bromide (KBr). 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 confirm 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 Potassium Bromide lot KBRO-0123-00011 that completed twenty-four (24) months of long-term stability in May 2025. The study includes the analyses listed in Table 1.

TABLE 1. STABILITY SPECIFICATIONS

Analysis	Specification
Absorbance (1M)	Monitor @ 260 nm
	Monitor @ 280 nm
Assay	98.0 – 100.5%
Limit of Chlorine	0.6% maximum
Loss on Drying	1.0% maximum

The quantitative 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 Potassium Bromide (KBr). The following Product Codes are commercially available.

- KBRO-2201
- KBRO-2220
- KBRO-2301
- KBRO-2302

2. REFERENCES:

- 2.1. BSI-LST-0152, Potassium Bromide Stability Data Card
- 2.2. BSI-SOP-0136, Stability Testing Program
- 2.3. BSI-SOP-0146, Stability Inventory
- 2.4. BSI-SOP-0289, Stability Indication Protocol
- 2.5. Current Ph. Eur. Current Edition
- 2.6. Current USP-NF
- 2.7. ICH Q1E

3. SAMPLE DESIGNATION:

- 3.1. Samples initially placed on the stability program consisted of one lot of Potassium Bromide. Stability samples from this batch were put into P/P packaging configuration. The samples were packaged in accordance with Stability Inventory DCN: BSI-SOP-0146. Reference Table 2, below, 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 HDPE pail and sealed.

4. STORAGE:

- 4.1. The USP packaging and storage requirements for Potassium Bromide are to be in well-closed containers stored at room temperature. For this study, the samples were stored in the Long-Term Stability Chamber H03SC01, at the Bangor, PA facility from May 2023 until the last sample time point in May 2024. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature ($25^{\circ}\text{C} \pm 2$) and relative humidity ($60\%\text{RH} \pm 5$). The conditions for the period of this study are detailed in Table 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.

TABLE 3. STORAGE CONDITIONS

Condition	Specification	Value
Minimum Temperature	23-27°C	21.81°C
Maximum Temperature		26.20°C
Average Temperature		25.33°C
Average Mean Kinetic Temperature	Monitor	25.33°C
Minimum Humidity	55-65%RH	43.6%RH
Maximum Humidity		80.5%RH
Average Humidity		61.4%RH

5. INVESTIGATIONS:

- 5.1. **BDI24-13**, Out of range humidity 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 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 on the current list of materials in the stability chamber.
- 5.2. **BDI24-126**: Out of specification humidity of 54.4% for H03SC01 occurred on 8/15/24. Upon inspection, it was found that this was due to a blown 20-amp fuse. The fuse was replaced and the humidity returned to specification. There was no impact to the materials in the stability chamber.
- 5.3. **BSI-DI25-0115**: The weekly check of the MadgeTech loggers was not performed for the week of 5/16/25. There was no impact on the product as the check was performed the week before and the week after and no abnormalities were observed. Additionally, there was no data loss or instances of loggers not recording during this time.

6. LOT EVALUATION:

TABLE 4. KBRO-0123-00011 P/P

Time Point	Analyses/Specifications				
	Absorbance (1M)		Assay	Limit of Chlorine	Loss on Drying
	Monitor @ 260 nm	Monitor @ 280 nm	98.5 – 100.5%	0.6% maximum	1.0% maximum
T₀	0.0058	0.0030	100.01%	<0.01%	0.0867%
T₃	0.0087	0.0056	99.16%	<0.01%	0.0572%
T₆	0.0050	0.0036	99.10%	<0.01%	0.0426%
T₉	0.0101	0.0065	98.65%	0.01%	0.0233%
T₁₂	0.0101	0.0065	98.84%	<0.01%	0.0209%
T₁₈	0.0105	0.0069	98.77%	<0.01%	<0.0074%
T₂₄	0.0082	0.0045	99.49%	<0.01%	0.0247%

- **Remaining Testing Interval pull dates**

- T = 36; Scheduled for May 11, 2026
- T = 48; Scheduled for May 11, 2027
- T = 60; Scheduled for May 11, 2028

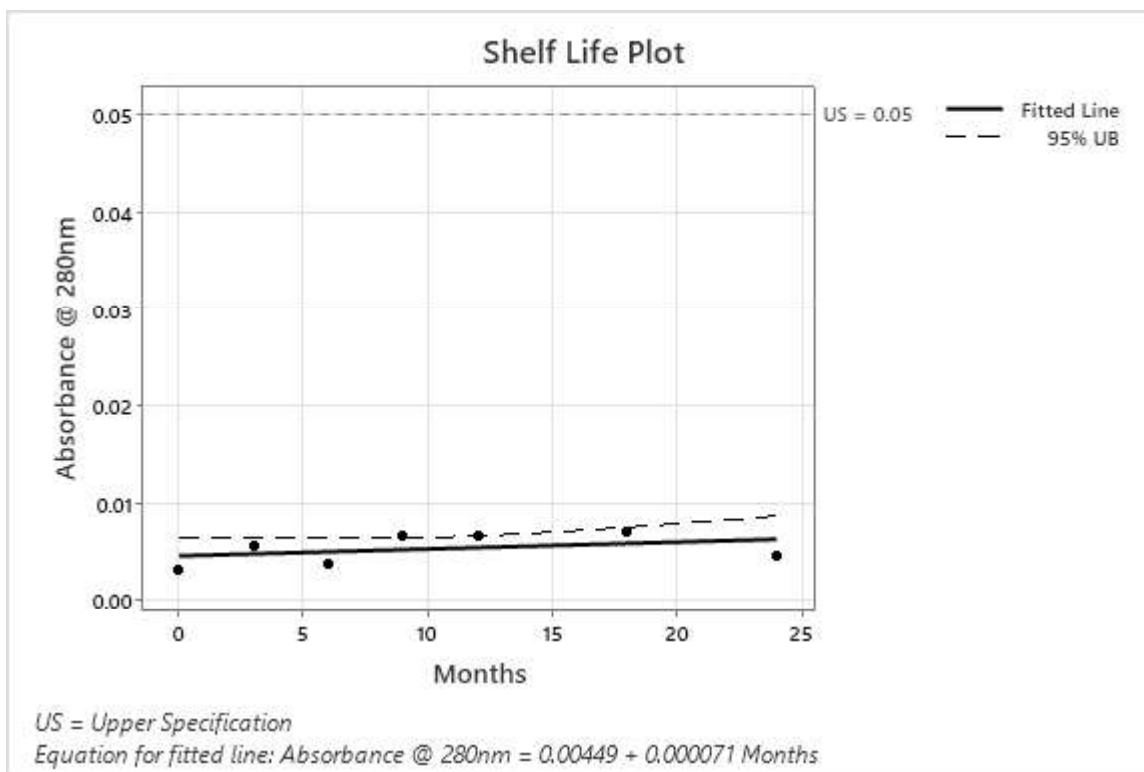


FIGURE 1. 1M ABSORBANCE @ 280 NM

The specification for absorbance at 280 nm is monitor. An arbitrary specification of 0.05 a.u. was used for the purposes of this report. No Shelf-Life was able to be determined for Absorbance at 280 nm, 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.

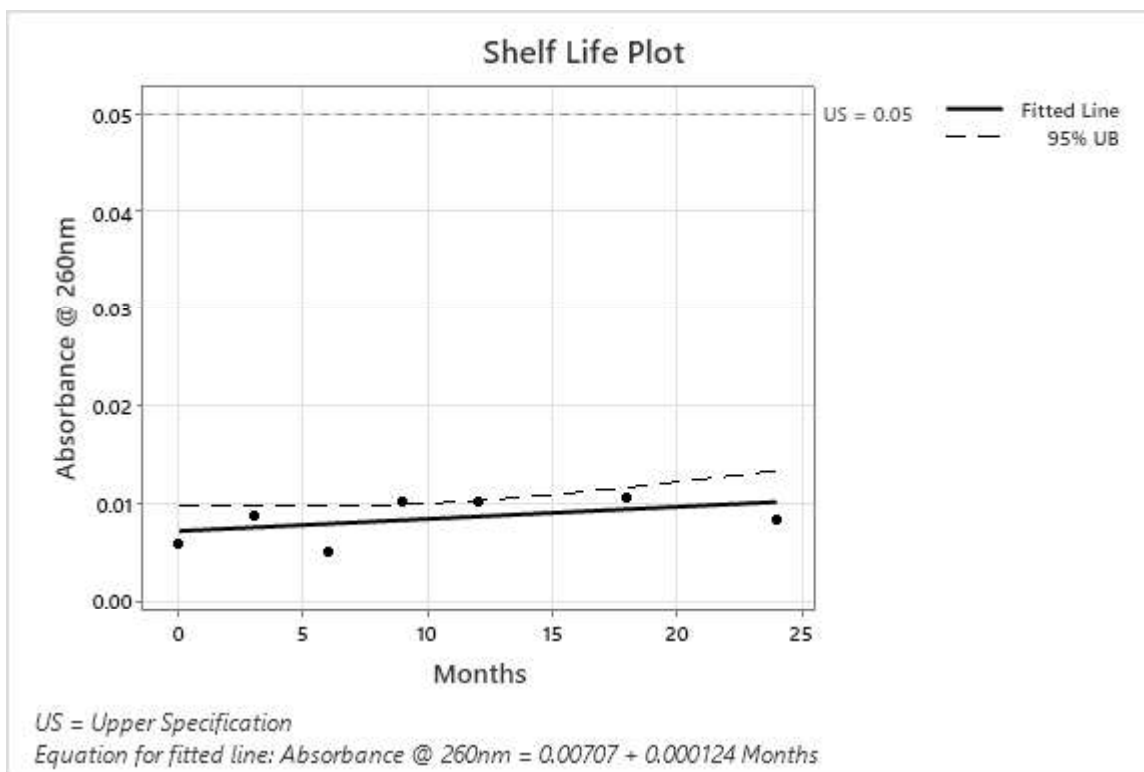
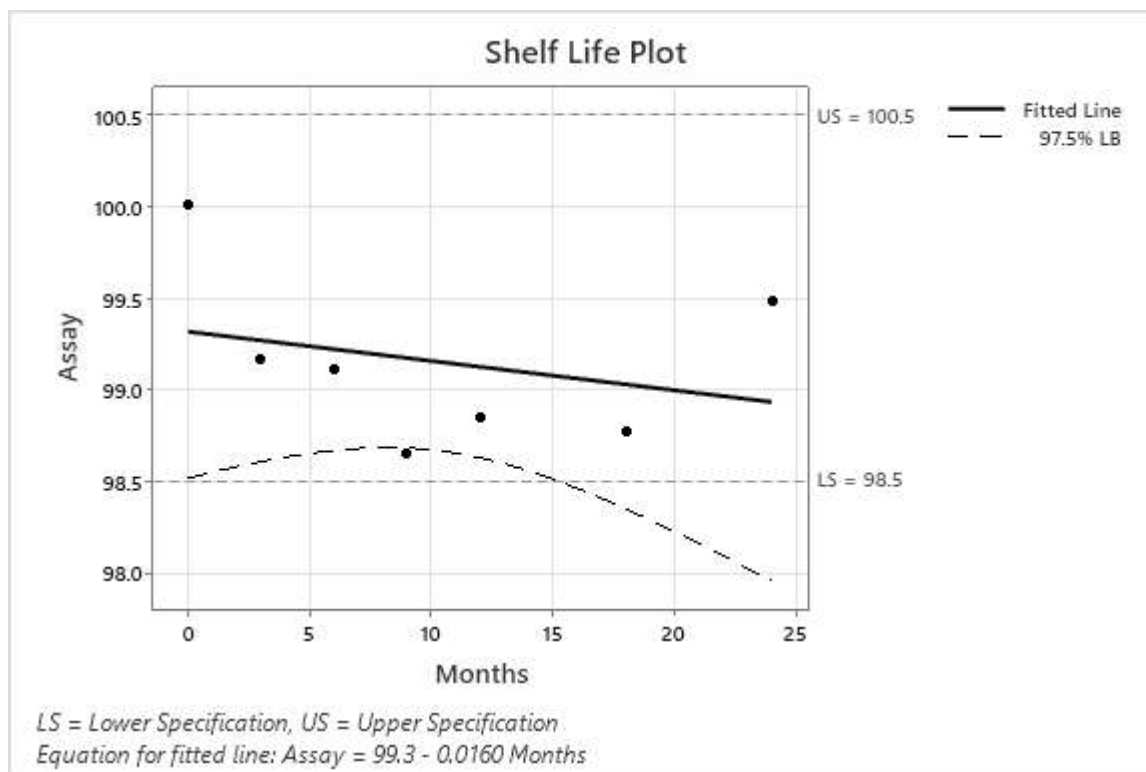


FIGURE 2. 1M ABSORBANCE @ 260 NM

The specification for absorbance at 260 nm is monitor. An arbitrary specification of 0.05 a.u. was used for the purposes of this report. No Shelf-Life was able to be determined for Absorbance at 260 nm, 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.

**FIGURE 3. ASSAY**

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 or expiration of this material.

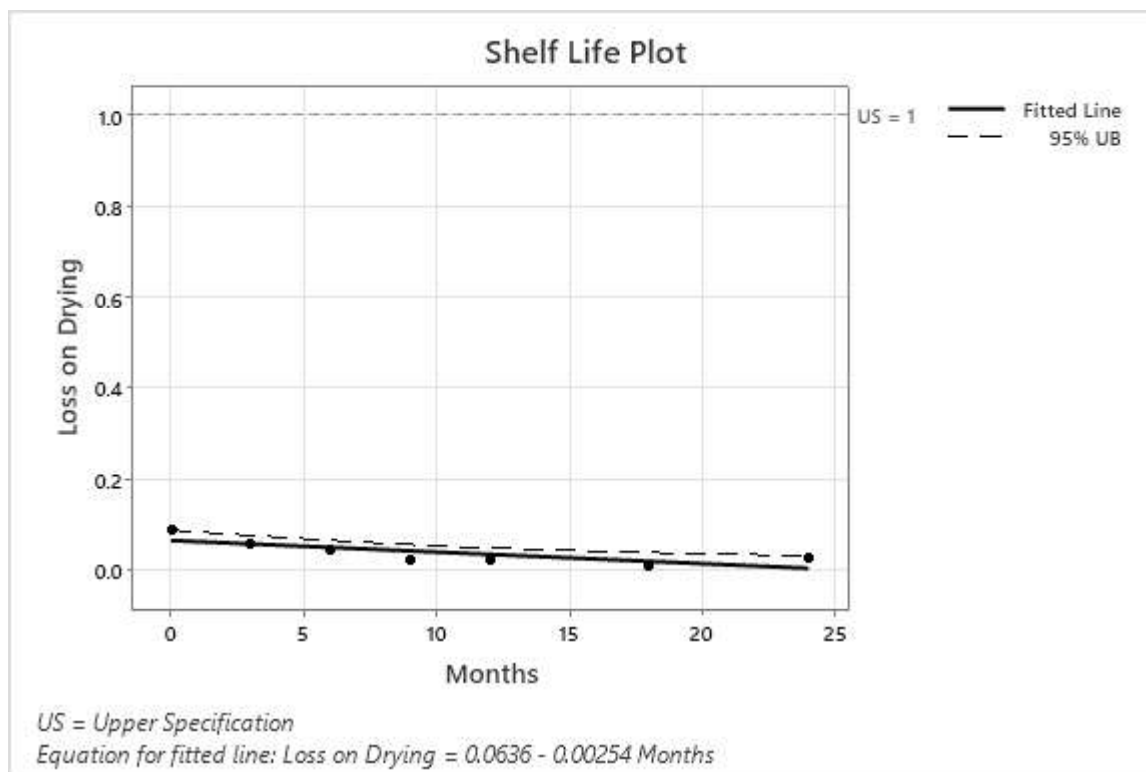


FIGURE 4. LOSS ON DRYING

No Shelf-Life was able to be determined for Loss on Drying, 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.

7. CONCLUSION:

All data met the specifications set forth in the Stability Testing Program for this 2023 lot when packaged in P/P packaging. 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. The data obtained during this stability study indicates that Potassium Bromide material packaged in P/P packaging is stable for 24 months with no shelf life determined for any quantitative analysis analyzed. The data in this report supports the currently assigned 24-month retest and 36-month expiration date.

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 real time 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 and the product has an established shelf life, the batch will be withdrawn from the market through communication with any 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.