BIOSPECTRA
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POTASSIUM BROMIDE 2022 VALIDATION LOTS LONG-TERM STABILITY REPORT

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1. OVERVIEW:

The purpose of this report is to analyze and conclude 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 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 validation lots KBRO-0122-00024-PV, KBRO-0122-00025-PV and KBRO-0122-00026-PV that completed thirty-six (36) months of long-term stability in April 2025. The study included the analyses listed in Table 1 below.

TABLE 1. STABILITY SPECIFICATIONS

Analyses	Specifications
Absorbance 1M @ 280 nm	Monitor
Absorbance 1M @ 260 nm	Monitor
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. Current Ph. Eur.
2.5. Current USP-NF
2.6. ICH Q1E

3. SAMPLE DESIGNATION:

3.1. Samples initially placed on the stability program consisted of three validation lots of Potassium Bromide. Stability samples from this batch were put into 2P/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 customers.

TABLE 2. PACKAGING DETAILS

Packaging Configuration	Packaging Description
2 Poly/Poly (2P/P)	Samples are packaged into small polyethylene bags and sealed with a zip tie. All individual samples are then placed into a larger polyethylene bag and sealed with a zip tie. This bag will then get placed into a HDPE drum.

4. STORAGE:

4.1. The 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 controlled temperature Zone J warehouse of the Bangor, PA facility from April 2022 until April 2025. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature (15-30°C) and humidity (monitor). The conditions for the period of this study are detailed in Table 3. Section 5 will include any excursions from these conditions that resulted in an investigation.

TABLE 3. STORAGE CONDITIONS

Condition	Specification	Value
Minimum Temperature	15 - 30°C	11.71°C
Maximum Temperature		38.92°C
Average Temperature		19.77°C
Average Mean Kinetic Temperature	≤25°C	19.78°C
Minimum Humidity	Monitor	3.4%
Maximum Humidity		94.3%
Average Humidity		38.5%

5. INVESTIGATIONS:

5.1. **BDI22-266:** During the month of July 2022 one of the MadgeTech data loggers (BWJ-6) stopped recording on 7/20/22 due to the logger being knocked from its bracket and the battery dislodged. There is no impact to the product as the other temperature loggers did not record any temperatures outside of the specifications.

5.2. **BDI22-272:** During the month of September 2022 one of the MadgeTech data loggers (BWJ-1) stopped recording due to a dislodged battery. There is no impact to the product as the other temperature loggers did not record any temperatures outside of the specifications.

5.3. **BDI22-330:** During the October 2022 temperature and humidity data collection, it was observed that a single data point was outside of the temperature specification on the high end for one logger while no other stability logger reported OOS results. The temperature reading was only OOS for 10 minutes and did not have any impact on the product.

5.4. **BDI24-129:** During the month of August 2024, MadgeTech data logger BWJ-1 did not download all the data from the monthly recording period due to a lost connection. There is no impact to the quality of the product stored in the Zone J warehouse as all surrounding loggers remained within temperature and humidity specifications.

5.5. **BDI24-159:** During the October 2024 temperature and humidity data collection, it was noted that the MadgeTech logger S/N P57558 battery had died, resulting in no data collection during a time span of 10/30/24-11/1/24. There is no impact to the quality of the product stored in the Zone J warehouse as all surrounding loggers remained within temperature and humidity specifications.

5.6. **BDI24-174:** During the November 2024 temperature and humidity data collection, it was observed that the temperature in the Zone J warehouse fell below the minimum requirement of 15°C. There is no impact to the product stored in the Zone J warehouse as the average readings and Mean Kinetic Temperature for all data loggers remained within the 15-30°C temperature specification.

6. LOT EVALUATION:

TABLE 4. KBRO-0122-00024-PV 2P/P

Time Point	Analyses/Specifications				
	Absorbance 1M (280nm)	Absorbance 1M (260nm)	Assay	Limit of Chlorine	Loss on Drying
	Monitor		98.0 – 100.5%	0.6% maximum	1.0% maximum
T_0	0.0011	0.0037	99.65%	<0.01%	0.1349%
T_3	0.0022	0.0051	98.48%	<0.01%	0.1358%
T_6	0.0041	0.0074	98.28%	<0.01%	0.0433%
T_9	0.0054	0.0108	99.48%	<0.01%	0.0323%
T_{12}	0.0048	0.0081	98.42%	0.01%	0.0405%
T_{18}	0.0030	0.0059	99.63%	<0.01%	0.0207%
T_{24}	0.0043	0.0076	98.85%	<0.01%	0.0307%
T_{36}	0.0060	0.0117	99.88%	0.01%	0.0539%

Remaining Testing Interval Pull Dates:

- T=48; scheduled for 4/4/26
- T=60; scheduled for 4/4/27

TABLE 5. KBRO-0122-00025-PV 2P/P

Time Point	Analyses/Specifications				
	Absorbance 1M (280nm)	Absorbance 1M (260nm)	Assay	Limit of Chlorine	Loss on Drying
	Monitor		98.0 – 100.5%	0.6% maximum	1.0% maximum
T_0	<0.003	0.0013	99.34%	0.02%	0.0951%
T_3	0.0021	0.0047	98.89%	0.01%	0.0450%
T_6	0.0039	0.0073	98.35%	<0.01%	0.0380%
T_9	0.0073	0.0133	98.52%	<0.01%	0.0357%
T_{12}	0.0045	0.0081	98.48%	0.01%	0.0327%
T_{18}	0.0040	0.0071	99.75%	<0.01%	0.0228%
T_{24}	0.0052	0.0084	99.14%	<0.01%	<0.0058%
T_{36}	0.0064	0.0115	99.85%	<0.01%	0.0131%

Remaining Testing Interval Pull Dates:

- T=48; scheduled for 4/4/26
- T=60; scheduled for 4/4/27

TABLE 6. KBRO-0122-00026-PV 2P/P

Time Point	Analyses/Specifications				
	Absorbance 1M (280nm)	Absorbance 1M (260nm)	Assay	Limit of Chlorine	Loss on Drying
	Monitor		98.0 – 100.5%	0.6% maximum	1.0% maximum
T_0	<0.003	0.0013	98.60%	<0.01%	0.0473%
T_3	0.0021	0.0049	98.65%	<0.01%	0.0219%
T_6	0.0021	0.0054	98.53%	0.01%	0.0156%
T_9	0.0060	0.0119	99.19%	<0.01%	0.0185%
T_{12}	0.0040	0.0086	98.95%	0.01%	0.0220%
T_{18}	0.0025	0.0054	99.56%	<0.01%	0.0124%
T_{24}	0.0051	0.0083	98.86%	<0.01%	<0.0066%
T_{36}	0.0064	0.0106	99.89%	0.01%	<0.0076%

Remaining Testing Interval Pull Dates:

- T=48; scheduled for 4/4/26
- T=60; scheduled for 4/4/27

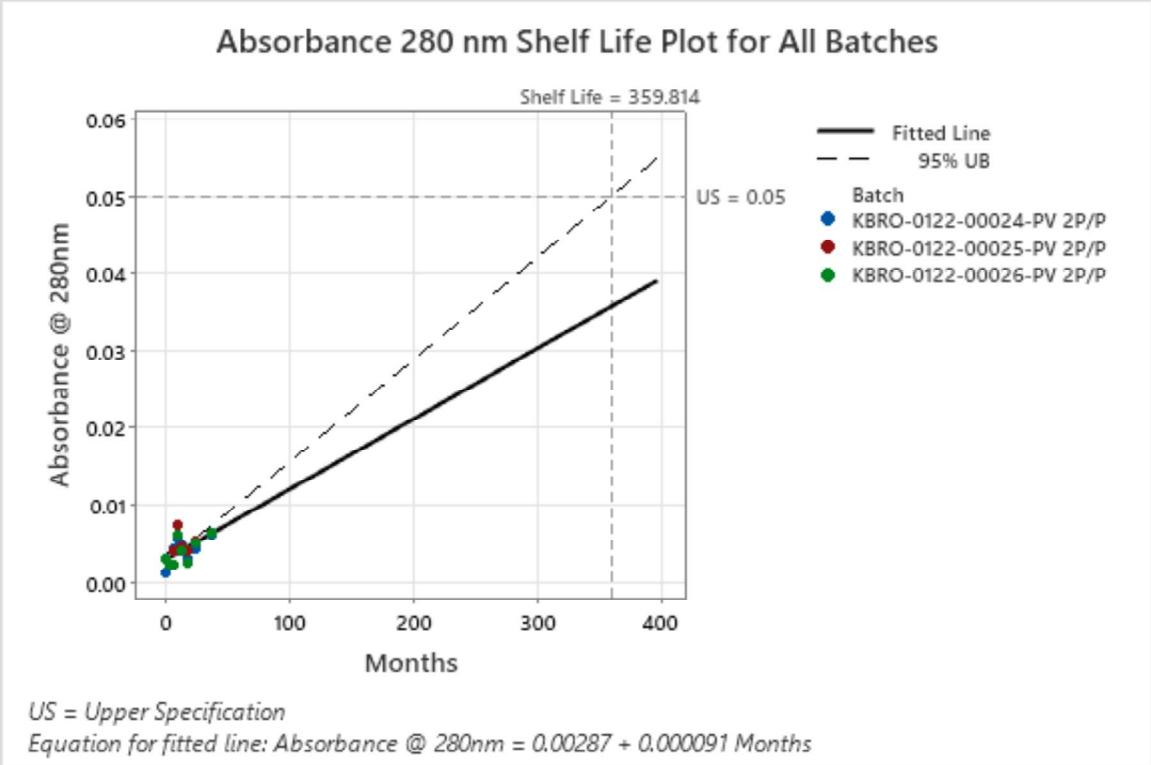

FIGURE 1. 1M ABSORBANCE @ 280 NM

The specification for absorbance at 280 nm is monitor. An arbitrary specification of 0.05 a.u. max. was used for the purposes of this report. The predicted Shelf-Life for Absorbance at 280 nm was determined to be 359.814 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.

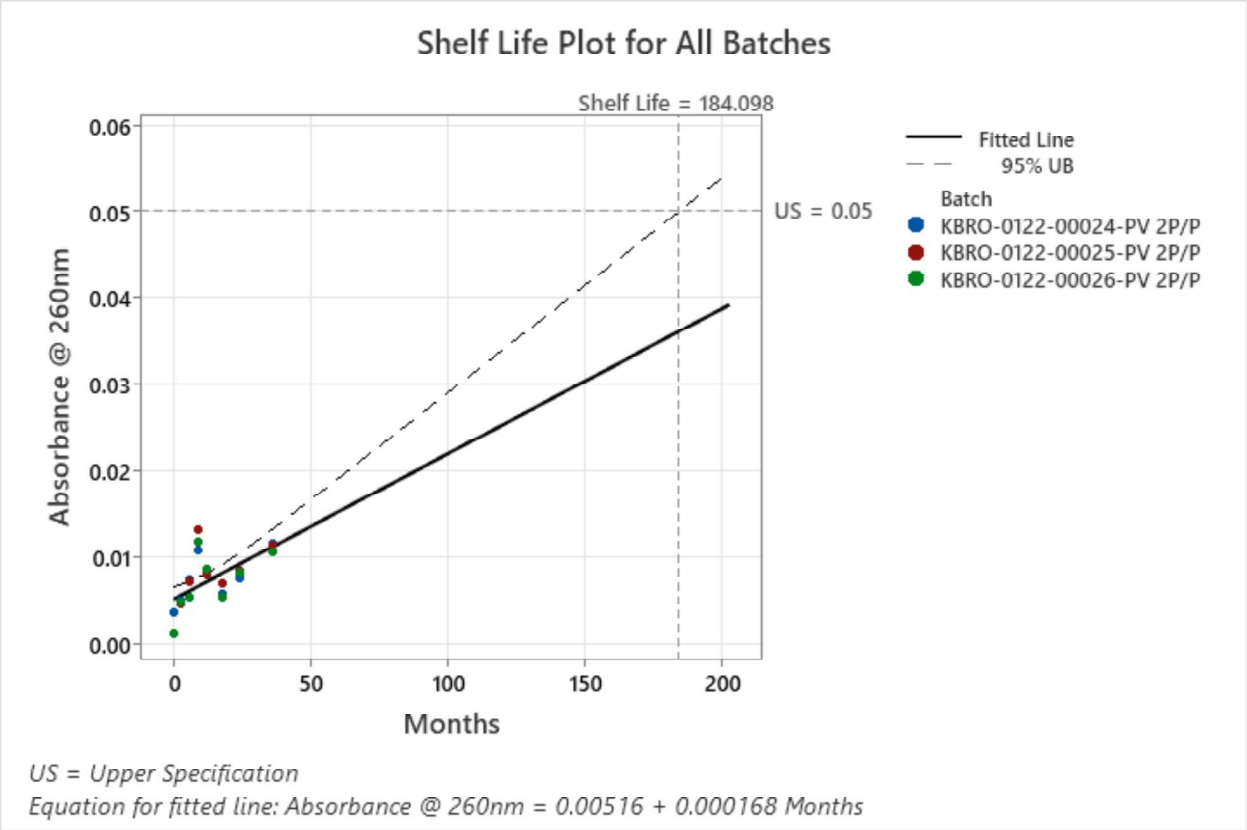

FIGURE 2. 1M ABSORBANCE @ 260 NM

The specification for absorbance at 260 nm is monitor. An arbitrary specification of 0.05 a.u. max. was used for the purposes of this report. The predicted Shelf-Life for Absorbance at 260 nm was determined to be 184.098 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.

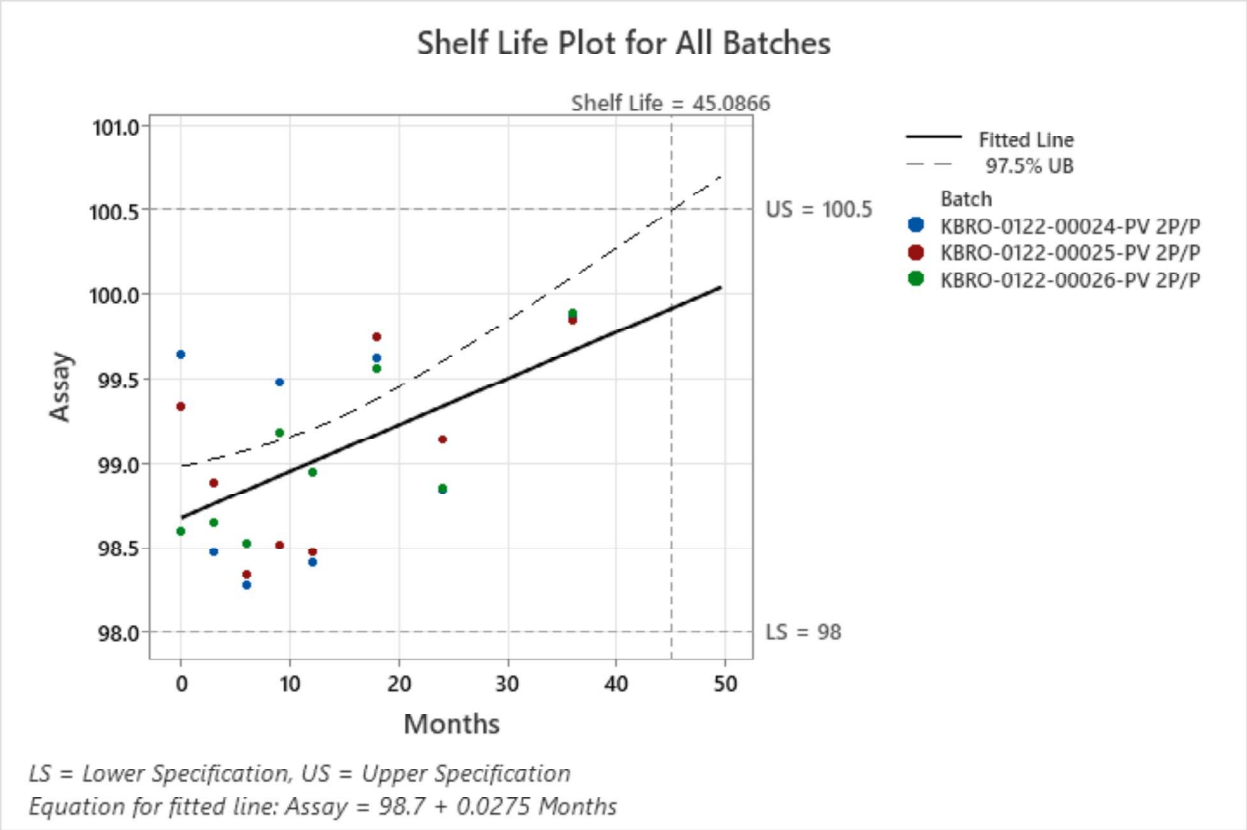

FIGURE 3. ASSAY

The predicted Shelf-Life for Assay was determined to be 45.0866 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest or expiration of this material.

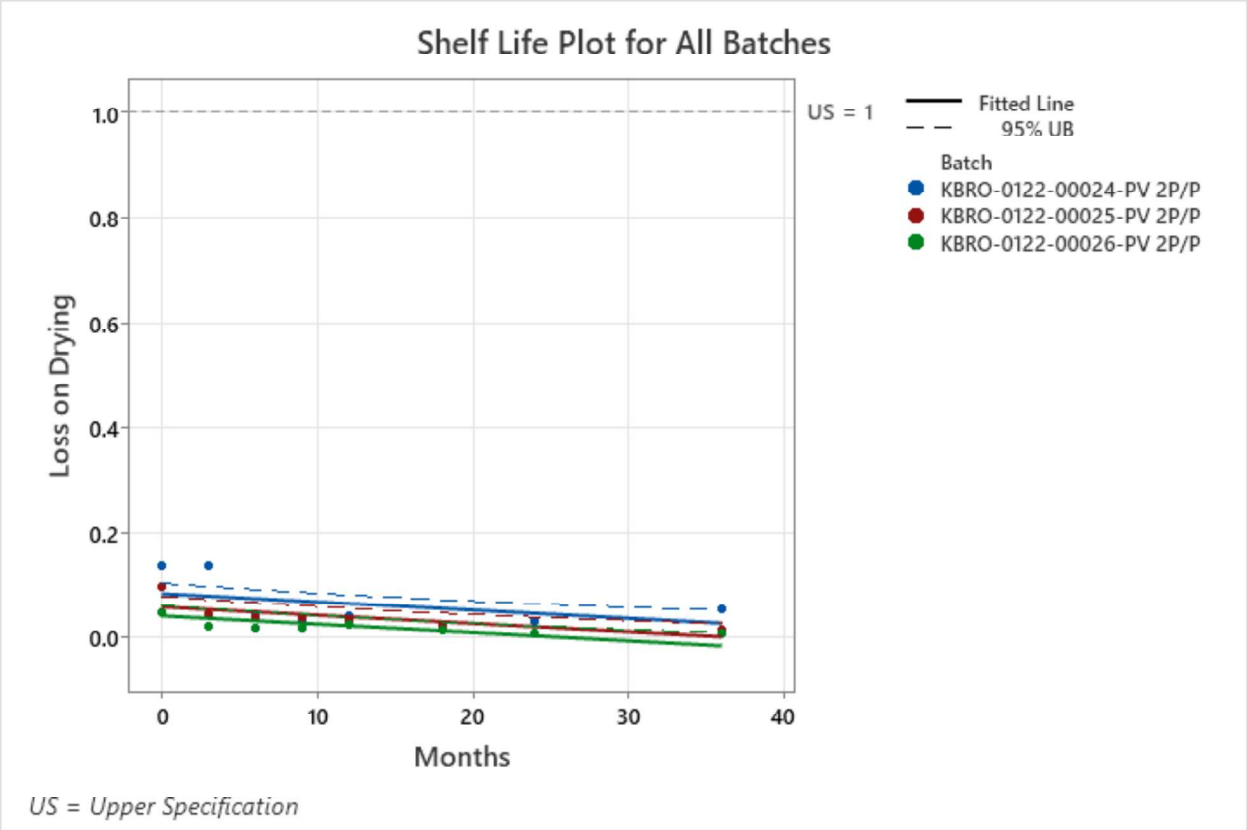

FIGURE 4. LOSS ON DRYING

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.

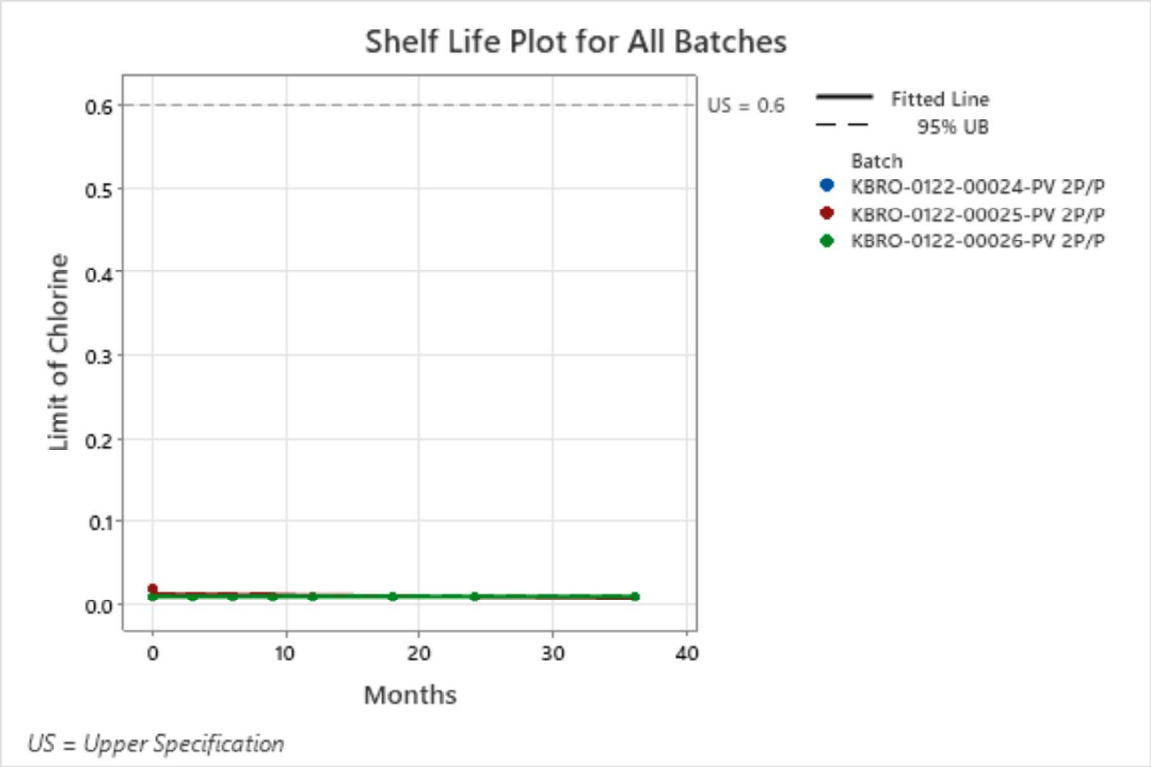

FIGURE 5. LIMIT OF CHLORINE

No Shelf-Life was able to be determined for Limit of Chlorine, 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 these validation lots when packaged in 2P/P packaging. In accordance with ICH Q1E, the retest date may be proposed for up to 2*x*, 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 2P/P packaging is stable for 36 months. This data supports the currently assigned 24-month retest date 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.