



100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

POTASSIUM BROMIDE
REAL-TIME STABILITY REPORT:
PB2201-143-0517

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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 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 Real Time Stability analysis will assess the stability of Potassium Bromide lot PB2201-143-0517 that completed three years of real-time stability in May 2020. The study included the following analyses: Absorbance (1M), Assay, Limit of Chlorine, and Loss on Drying. 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 Potassium Bromide (KBr). The following Product Codes are commercially available.

- KBRO-2201 (Historical PB2201)
- KBRO-2220 (Historical PB2220)
- KBRO-2301 (Historical PB2301)

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 Q1

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 2P/P packaging configuration. The samples were packaged in accordance with Stability Inventory DCN: BSI-SOP-0146. Reference Table 1, 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 1: PACKAGING DETAILS

Packaging Configuration	Packaging Description
2P/P	Samples are packaged into small poly bags and sealed with a zip tie. All individual samples are then placed into a larger poly bag, sealed with a zip tie, and then are placed into a poly drum.

4. STORAGE:

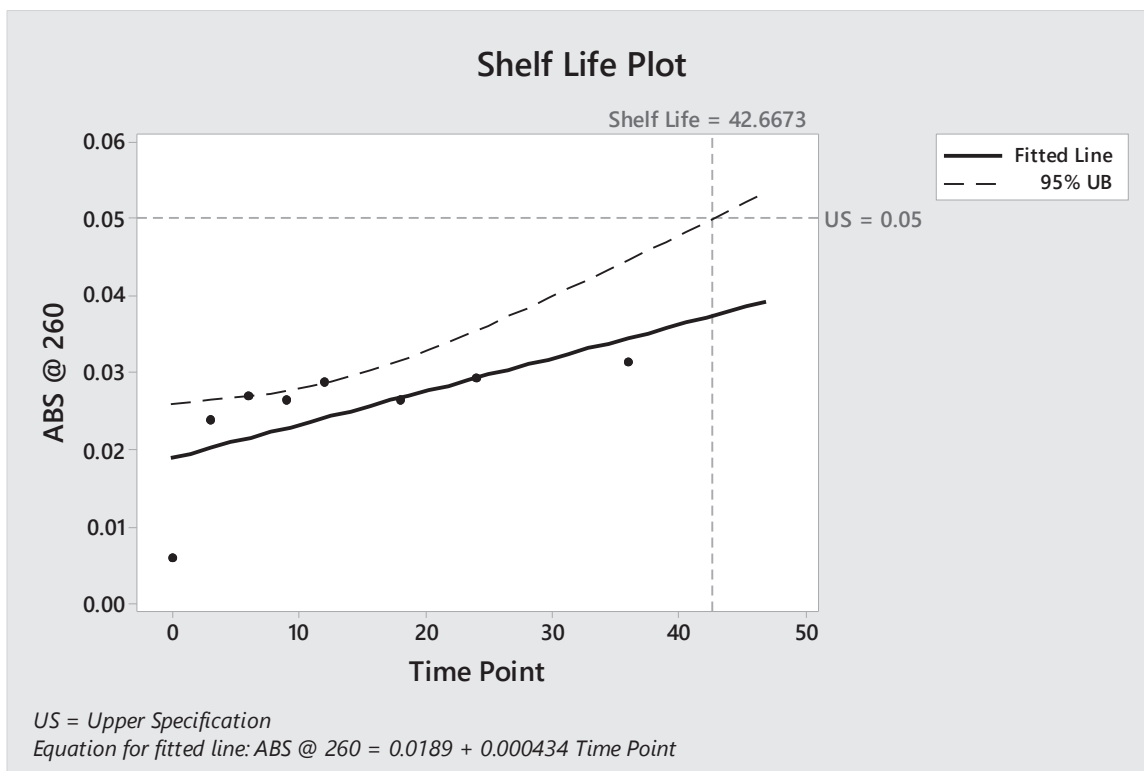
- 4.1. The USP Packaging and Storage requirements for Potassium Bromide are to be in well-closed containers stored at room temperature. For this study, the samples were stored in the Controlled Temperature Room, L05 located in Zone L at the Bangor, PA facility from May 2017 until the last sample time point in May 2020. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature (15-30°C) and humidity (monitor). For this period, the maximum temperature recorded was 27.89°C, the minimum temperature was 13.65°C, the average temperature was 21.35°C, and the Average Mean Kinetic Temperature was 21.38°C. Section 5 will include any excursions from these conditions that resulted in an investigation.

5. INVESTIGATIONS:

- 5.1. **BDI18-27:** The L05 Climate Controlled Storage Room had below specification readings for temperature on multiple dates ranging from 12/19/17 through 3/19/18. The alarms did not trigger due to how they were established. Alarms were reconfigured to prevent this from happening again.
- 5.2. **BDI19-01:** Temperature and Humidity Monitoring assessments were not completed on a quarterly basis for multiple locations, including L05. Additionally, upon review of data the minimum temperature was below the specification for readings on 4/4/18. The alarms did not trigger due to how they were established. Alarms were reconfigured to prevent this from happening again.

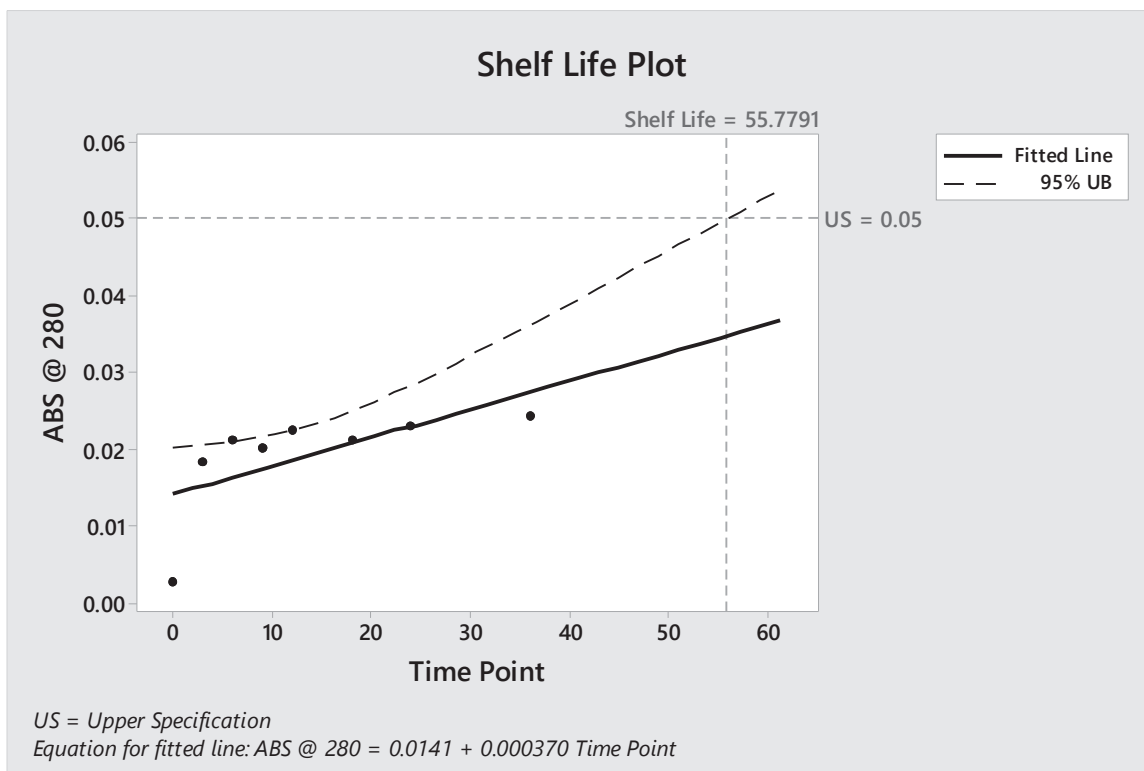
6. LOT EVALUATION:**TABLE 2: RESULT OF REAL TIME STABILITY ANALYSES**

Lot Number	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
PB2201-143-0517	Absorbance (1M) @ 260 nm	Monitor	0.0057	0.0237	0.0268	0.0264	0.0287	0.0264	0.0291	0.0312
	Absorbance (1M) @ 280 nm	Monitor	0.0027	0.0182	0.0212	0.0201	0.0224	0.0211	0.0230	0.0243
	Assay	98.0 – 100.5%	99.74%	100.05%	98.06%	98.97%	99.92%	98.66%	98.50%	99.28%
	Limit of Chlorine	0.6% maximum	<0.01%	0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%
	Loss on Drying	1.0% maximum	0.0449%	0.0183%	0.0162%	0.0150%	0.0069%	0.0322%	0.0086%	0.0208%

GRAPH 1: 1M ABSORBANCE @ 260 NM

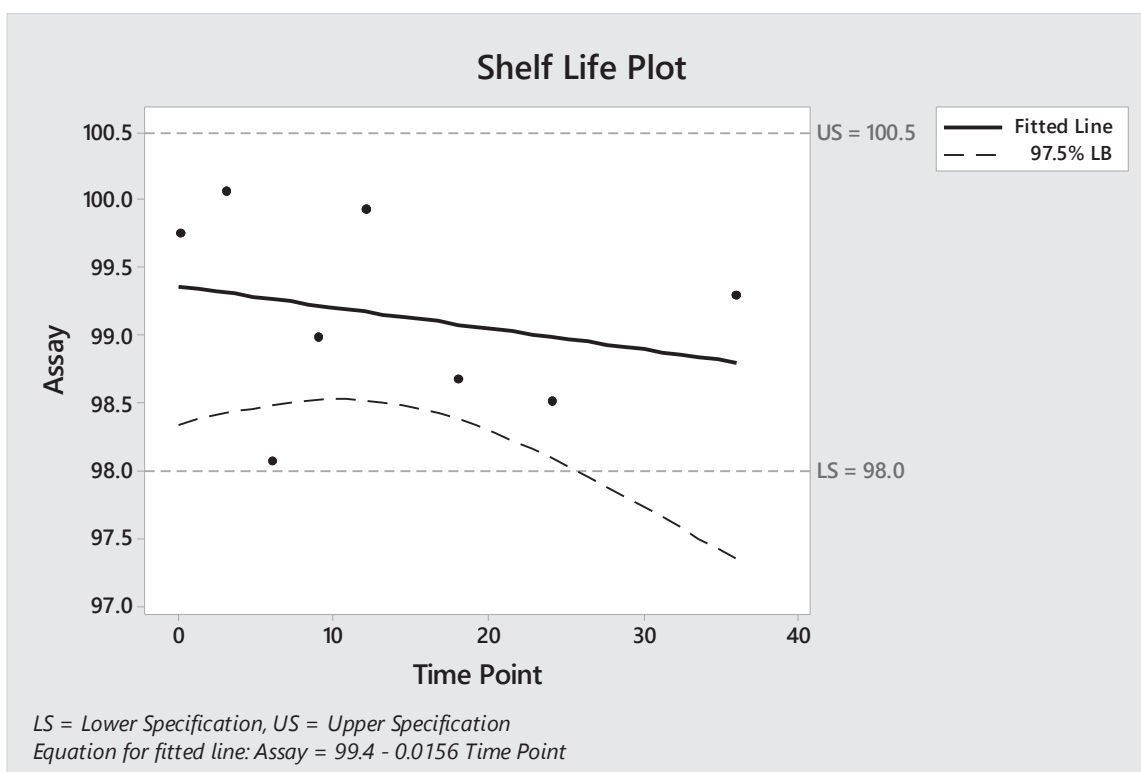
- 6.1. The predicted Shelf-Life for 1M Absorbance @ 260 nm was determined to be 42.6673 months. This shelf-life is beyond the 36-month stability study, therefore, there is no impact to the product or current assigned retest or expiration of this material.

GRAPH 2: 1M ABSORBANCE @ 280 NM

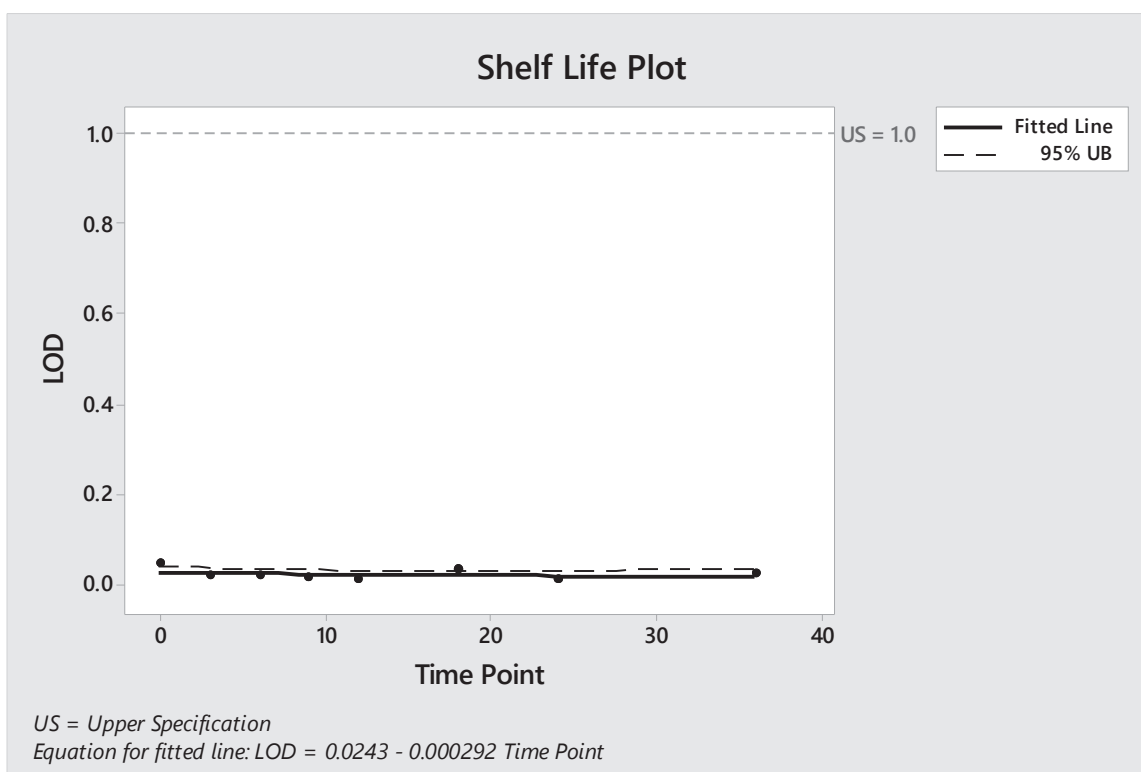


- 6.2. The predicted Shelf-Life for 1M Absorbance @ 280 nm was determined to be 55.7791 months. This shelf-life is beyond the 36-month stability study, therefore, there is no impact to the product or currently assigned retest or expiration of this material.

GRAPH 3: ASSAY



- 6.3. 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.

GRAPH 4: LOSS ON DRYING

- 6.4. 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:

- 7.1. All data met the specifications set forth in the Stability Testing Program. In accordance with ICH Q1E 2.4.2.1, the retest data 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 successful completion of this 36-month stability study can confirm that all codes for this material are stable for up to 3 years. A 2-year retest date or a 3-year expiry date may be issued for Potassium Bromide manufactured at BioSpectra at the Bangor, PA facility.

8. STATEMENT OF COMMITMENT:

- 8.1. BioSpectra is responsible for the following regarding API Stability Data in this report:
- 8.1.1 All ongoing stability data points obtained from this program will be submitted to the VMF on an annual basis.
 - 8.1.2 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.
 - 8.1.2.1 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.

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

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POTASSIUM BROMIDE, KBRO-2220

LONG-TERM AND ACCELERATED STABILITY

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Potassium Bromide KBRO-2220 Stability Assessment

Overview:

This study summarizes and assesses the completed accelerated stability analysis of Potassium Bromide Bio Active grade, product code KBRO-2220, manufactured at BioSpectra's Bangor, PA facility. Additionally, the completed and ongoing long-term stability analyses of this product are also summarized. The stability studies are performed to evaluate product quality attributes and stability over time under the appropriate storage conditions.

This study includes the following quantitative analyses: Absorbance (1M) at 280nm and 260nm, Assay (%), Limit of Chlorine (%), and Loss on Drying (%). The results of these tests will be analyzed in shelf life plots. Assay (%) was deemed a stability indicating analysis, and the Limit of Chlorine was also included as a stability indicating analysis due to the dependency of this analysis on the assay method. Absorbance (1M) was not shown to be stability indicating, but it is included for monitoring purposes. Lastly, Loss on Drying (%) analysis is a requirement per the Stability Testing Program.

Long-term stability testing is performed every three months during the first year, every six months for the second year, and annually for each subsequent year for a total of three years. Accelerated stability testing is performed every month for a period of six months. Testing intervals are indicated by T_n, where n represents the number of months on stability.

The accelerated stability program for the 2013 Potassium Bromide Bio Active grade process validation lots was concluded in June 2014, with the long-term stability concluding in October 2016. Long-term stability for 2015 Potassium Bromide Bio Active Grade process validation lots concluded in May 2018 and June 2018. Long-term stability for additional 2015 Potassium Bromide Bio Active Grade process validation lots concluded in October 2018.

Long-term stability samples for ongoing analysis will continue to be pulled at the designated testing intervals. Long-term stability analysis will also continue to be performed on any future process validation lots manufactured, and at least one cGMP manufactured lot of Potassium Bromide Bio Active grade product will be placed on stability per year.

Sample Designation:

The material analyzed on Long-Term Stability consists of multiple Potassium Bromide Bio Active grade lots. Long-term stability samples were packaged as Polyethylene (Poly)/Polyethylene (Poly) (P/P), or 2 Polyethylene (Poly)/Polyethylene (Poly) (2P/P). Potassium Bromide Bio Active Grade lots manufactured in 2019 and 2020 were placed on Long-Term stability and will reported on at the appropriate time. The material analyzed on Accelerated Stability consists of the three 2013 process validation lots. Accelerated stability samples were packaged in the P/P packaging configuration.

Storage:

Long-term stability samples placed on stability in 2018 or earlier were stored in the QC storage area located in the Zone M warehouse of the Bangor, PA facility. Temperature and humidity conditions were continuously monitored, with temperatures ranging from 10°C - 40°C. Beginning in August 2018, long-term stability samples were stored in the L05 Climate Controlled Storage Room, located in Zone L of the Bangor facility. The storage conditions are 15°C - 30°C, with a mean kinetic temperature ≤25°C.

Accelerated stability samples were stored in the Accelerated Stability Chamber, located in Zone H of the Bangor facility. The allowable storage conditions are temperatures of 40°C ± 2°C, with relative

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humidity of 75% RH \pm 5% RH. Storage conditions for both long-term and accelerated stability samples are continuously measured and recorded utilizing MadgeTech data loggers.

Conclusion:

All reported long-term stability data met the established specifications. A shelf life of 99.0261 months was predicted for absorbance at 280nm, which is well above the current retest date of 24 months. A shelf life of 68.8291 months was predicted for absorbance at 260nm, which is well above the current retest date of 24 months. A shelf life of 80.2643 months was predicted for assay (%), which is well above the current retest date of 24 months. A shelf life could not be predicted for the Loss on Drying or Limit of Chlorine analyses, as the mean response slopes were not significantly different from zero, indicating minimal degradation of the product.

All reported accelerated stability data met the established specifications. A shelf life of 6.61155 months was predicted for assay (%). This shelf life estimate is not a concern, as additional long-term stability data has been collected and shown Potassium Bromide assay (%) to be stable well over the reported two-year retest date with an estimated shelf life of 80.2643 months. A shelf life could not be predicted for the remainder of the accelerated stability analyses, as the mean response slope was not significantly different from zero.

Samples will continue to be pulled at the designated times through T₃₆, and analyzed to assess product stability and assign a shelf-life or retest date to the product. These results will be analyzed and reported on at the conclusion of the long-term stability study.

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Long-Term Stability Data**Table 1: Tabulated Summary of Long-Term Stability Data (P/P)**

Lot & Sample Designation	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
2013 Validation Lot 1 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0082	0.0042	0.0088	0.0120	0.0151	0.0209	0.0203	0.0202
		Monitor @ 260 nm	0.0119	0.0070	0.0124	0.0161	0.0198	0.0244	0.0254	0.0244
	Assay	98.0-100.5%	98.9	99.6	100.1	100.2	99.7	98.7	99.4	100.0
	Limit of Chlorine	0.6% maximum	0.02	0.02	0.01	0.01	0.04	0.06	0.04	0.01
	Loss on Drying	1.0% maximum	0.0079	0.0249	0.0118	0.0322	0.0318	0.0149	0.0595	0.0119
2013 Validation Lot 2 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0085	0.0077	0.0143	0.0168	0.0184	0.0160	0.0234	0.0163
		Monitor @ 260 nm	0.0114	0.0104	0.0182	0.0207	0.0219	0.0190	0.0274	0.0196
	Assay	98.0-100.5%	98.5	99.4	100.4	99.5	98.3	98.6	99.7	100.4
	Limit of Chlorine	0.6% maximum	0.18	0.02	0.02	0.01	0.03	0.06	0.01	<0.01
	Loss on Drying	1.0% maximum	0.2932	0.0232	0.0143	0.0222	0.0240	0.0174	0.0119	0.0285
2013 Validation Lot 3 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0060	0.0055	0.0086	0.0099	0.0130	0.0156	0.0246	0.0182
		Monitor @ 260 nm	0.0090	0.0088	0.0125	0.0138	0.0165	0.0194	0.0550	0.0230
	Assay	98.0-100.5%	99.2	99.7	99.9	100.1	99.7	98.3	99.4	100.2
	Limit of Chlorine	0.6% maximum	0.04	0.03	0.01	0.01	0.03	0.07	0.02	0.01
	Loss on Drying	1.0% maximum	<0.0050	0.0248	0.0124	0.0240	0.0117	0.0375	<0.0071	0.0095
2015 Validation Lot 1 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0032	0.0186	0.0101	0.0085	0.0051	0.0109	0.0135	0.0153
		Monitor @ 260 nm	0.0063	0.0236	0.0135	0.0120	0.0083	0.0155	0.0180	0.0200
	Assay	98.0-100.5%	98.6	98.1	98.5	98.6	99.9	99.9	98.7	100.1
	Limit of Chlorine	0.6% maximum	0.04	0.02	0.01	0.02	0.04	0.02	<0.01	<0.01
	Loss on Drying	1.0% maximum	0.4723	0.4594	0.2619	0.1738	0.0833	0.0476	0.0095	0.0384
2015 Validation Lot 2 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0064	0.0279	0.0132	0.0094	0.0075	0.0088	0.0133	0.0186
		Monitor @ 260 nm	0.0109	0.0351	0.0183	0.0144	0.0101	0.0141	0.0187	0.0260
	Assay	98.0-100.5%	98.5	98.3	98.3	98.6	99.6	99.4	99.6	99.1
	Limit of Chlorine	0.6% maximum	<0.01	0.02	0.02	0.02	0.02	<0.01	<0.01	0.01
	Loss on Drying	1.0% maximum	0.1549	0.3141	0.3165	0.3141	0.3185	0.2957	0.1329	0.0804

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Lot & Sample Designation	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
2015 Validation Lot 3 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0023	0.0197	0.0120	0.0077	0.0071	0.0105	0.0098	0.0138
		Monitor @ 260 nm	0.0053	0.0251	0.0160	0.0109	0.0101	0.0150	0.0136	0.0192
	Assay	98.0-100.5%	99.3	98.6	98.3	98.4	99.1	99.5	99.8	99.3
	Limit of Chlorine	0.6% maximum	0.01	0.02	<0.01	0.01	0.01	0.04	<0.01	<0.01
	Loss on Drying	1.0% maximum	0.1547	0.0214	0.0262	0.0214	<0.0071	0.0161	0.0397	<0.0071
2015 Validation Lot 4 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0029	0.0083	0.0109	0.0129	0.0148	0.0115	0.0112	0.0168
		Monitor @ 260 nm	0.0071	0.0140	0.0151	0.0170	0.0193	0.0157	0.0159	0.0215
	Assay	98.0-100.5%	98.1	98.4	99.6	98.9	99.6	98.9	99.7	99.3
	Limit of Chlorine	0.6% maximum	0.04	0.02	<0.01	0.01	0.01	<0.01	0.03	0.01
	Loss on Drying	1.0% maximum	0.0798	0.3759	0.3187	0.2405	0.1210	0.0666	0.0471	0.0249
2015 Validation Lot 5 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0024	0.0054	0.0093	0.0121	0.0141	0.0109	0.0156	0.0199
		Monitor @ 260 nm	0.0052	0.0084	0.0128	0.0162	0.0188	0.0151	0.0204	0.0255
	Assay	98.0-100.5%	100.1	98.8	99.3	98.5	99.2	98.2	99.4	99.3
	Limit of Chlorine	0.6% maximum	0.06	<0.01	0.02	<0.01	<0.01	0.01	<0.01	<0.01
	Loss on Drying	1.0% maximum	0.2767	0.3919	0.3213	0.0619	0.1400	0.0286	0.0445	0.0274
2015 Validation Lot 6 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0024	0.0078	0.0099	0.0096	0.0192	0.0081	0.0150	0.0175
		Monitor @ 260 nm	0.0050	0.0110	0.0134	0.0134	0.0239	0.0117	0.0194	0.0225
	Assay	98.0-100.5%	98.9	98.5	99.5	98.7	99.3	100.3	99.5	99.5
	Limit of Chlorine	0.6% maximum	0.03	0.01	0.02	0.02	0.02	<0.01	0.01	<0.01
	Loss on Drying	1.0% maximum	0.3457	0.3806	0.3475	0.1547	0.0618	0.0095	0.0308	0.0102
2015 Validation Lot 7 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0025	0.0089	0.0086	0.0129	0.0164	0.0103	0.0128	0.0154
		Monitor @ 260 nm	0.0057	0.0129	0.0125	0.0174	0.0215	0.0146	0.0175	0.0203
	Assay	98.0-100.5%	98.6	99.1	99.5	98.6	98.6	99.6	99.0	99.4
	Limit of Chlorine	0.6% maximum	0.04	0.02	<0.01	0.02	0.02	0.02	<0.01	<0.01
	Loss on Drying	1.0% maximum	0.5551	0.8107	0.8235	0.7044	0.4166	0.4356	0.1902	0.0776

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Lot & Sample Designation	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
2015 Validation Lot 8 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0141	0.0119	0.0139	0.0173	0.0184	0.0153	0.0155	0.0206
		Monitor @ 260 nm	0.0186	0.0160	0.0188	0.0221	0.0244	0.0204	0.0205	0.0255
	Assay	98.0-100.5%	99.7	98.7	98.8	99.5	98.9	99.3	100.0	98.6
	Limit of Chlorine	0.6% maximum	<0.01	0.02	<0.01	0.02	<0.01	<0.01	<0.01	<0.01
	Loss on Drying	1.0% maximum	0.1093	0.0642	0.0666	0.0285	0.0405	0.0119	0.0333	0.0117
2015 Validation Lot 9 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0109	0.0080	0.0137	0.0131	0.0169	0.0146	0.0147	0.0146
		Monitor @ 260 nm	0.0148	0.0126	0.0181	0.0173	0.0222	0.0207	0.0198	0.0189
	Assay	98.0-100.5%	99.7	99.3	98.7	99.4	99.3	98.9	99.8	99.5
	Limit of Chlorine	0.6% maximum	<0.01	0.02	0.01	0.01	<0.01	<0.01	0.01	<0.01
	Loss on Drying	1.0% maximum	0.2709	0.2915	<0.0070	0.1284	0.1070	<0.0075	0.0450	0.0114
2015 Validation Lot 10 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0079	0.0100	0.0056	0.0150	0.0122	0.0112	0.0123	0.0110
		Monitor @ 260 nm	0.0115	0.0142	0.0090	0.0191	0.0171	0.0161	0.0167	0.0154
	Assay	98.0-100.5%	98.9	99.1	99.8	99.1	99.0	98.5	99.7	98.7
	Limit of Chlorine	0.6% maximum	0.01	0.02	0.01	0.04	0.01	<0.01	0.02	<0.01
	Loss on Drying	1.0% maximum	0.5614	0.7113	0.5857	0.7118	0.6910	0.2762	0.2094	0.1032
2017 Validation Lot 1 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0009	0.0095	0.0089	0.0119	0.0144	0.0144	0.0137	11/13/2020
		Monitor @ 260 nm	0.0037	0.0142	0.0135	0.0167	0.0192	0.0189	0.0182	11/13/2020
	Assay	98.0-100.5%	98.6	99.4	99.2	99.5	99.0	99.4	99.0	11/13/2020
	Limit of Chlorine	0.6% maximum	<0.01	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	11/13/2020
	Loss on Drying	1.0% maximum	0.1191	0.0210	0.0110	0.0301	0.0568	0.0168	0.0206	11/13/2020
2017 Validation Lot 2 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0060	0.0087	0.0114	0.0204	0.0135	0.0146	0.0152	11/20/2020
		Monitor @ 260 nm	0.0100	0.0132	0.0164	0.0263	0.0180	0.0202	0.0198	11/20/2020
	Assay	98.0-100.5%	99.2	99.1	100.4	98.1	98.8	99.8	99.1	11/20/2020
	Limit of Chlorine	0.6% maximum	<0.01	<0.01	<0.01	<0.01	0.01	<0.01	<0.01	11/20/2020
	Loss on Drying	1.0% maximum	0.0614	0.0589	0.0119	0.0442	0.0626	0.0184	0.0253	11/20/2020

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Lot & Sample Designation	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
2017 Validation Lot 3 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0064	0.0082	0.0113	0.0174	0.0156	0.0132	0.0136	11/20/2020
		Monitor @ 260 nm	0.0108	0.0128	0.0164	0.0231	0.0205	0.0187	0.0182	11/20/2020
	Assay	98.0-100.5%	99.3	99.1	100.1	98.2	98.9	98.4	99.3	11/20/2020
	Limit of Chlorine	0.6% maximum	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	11/20/2020
	Loss on Drying	1.0% maximum	0.0816	0.0848	<0.0059	0.0551	0.1044	0.0409	0.0399	11/20/2020
2017 Validation Lot 4 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0036	0.0103	0.0112	0.0177	0.0167	0.0135	0.0188	11/20/2020
		Monitor @ 260 nm	0.0070	0.0149	0.0157	0.0233	0.0213	0.0185	0.0237	11/20/2020
	Assay	98.0-100.5%	99.0	99.3	100.2	98.1	99.0	98.8	99.2	11/20/2020
	Limit of Chlorine	0.6% maximum	<0.01	<0.01	<0.01	<0.01	0.01	<0.01	<0.01	11/20/2020
	Loss on Drying	1.0% maximum	0.1903	0.0333	0.0286	0.0339	0.0388	0.0159	0.0163	11/20/2020

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Table 2: Tabulated Summary of Long-Term Stability Data (2P/P)

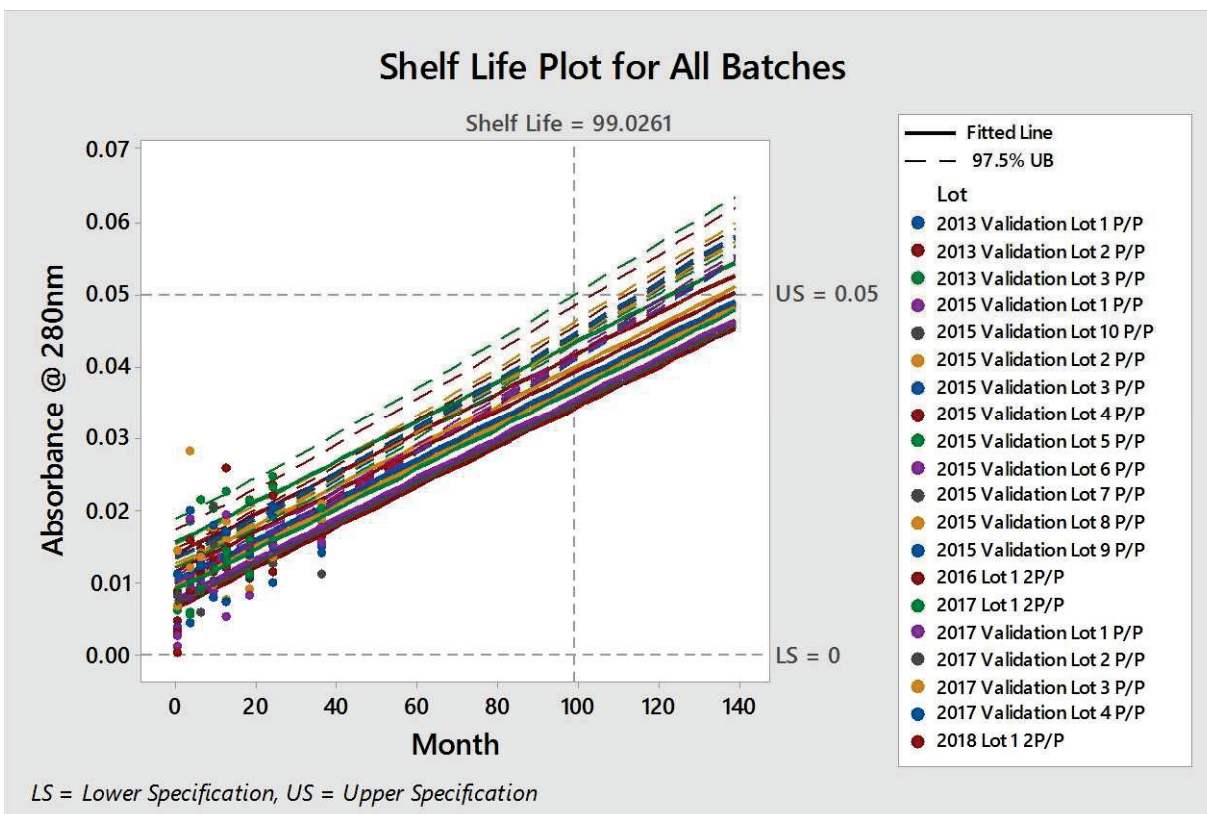
Lot & Sample Designation	Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
2016 Lot 1 2P/P	Absorbance (1M)	Monitor @ 280 nm	0.0044	0.0157	0.0134	0.0168	0.0257	BDI19-108	0.0219	7/3/2020
		Monitor @ 260 nm	0.0086	0.0212	0.0188	0.0232	0.0332	BDI19-108	0.0271	7/3/2020
	Assay	98.0-100.5%	99.1	100.2	98.5	99.5	99.8	BDI19-108	98.8	7/3/2020
	Limit of Chlorine	0.6% maximum	<0.01	<0.01	0.01	<0.01	<0.01	BDI19-108	<0.01	7/3/2020
	Loss on Drying	1.0% maximum	0.0619	0.0357	<0.0075	0.0207	0.0318	BDI19-108	0.0373	7/3/2020
2017 Lot 1 2P/P	Absorbance (1M)	Monitor @ 280 nm	0.0027	0.0182	0.0212	0.0201	0.0224	0.0211	0.0230	5/11/2020
		Monitor @ 260 nm	0.0057	0.0237	0.0268	0.0264	0.0287	0.0264	0.0291	5/11/2020
	Assay	98.0-100.5%	99.7	100.1	98.1	99.0	99.9	98.7	98.5	5/11/2020
	Limit of Chlorine	0.6% maximum	<0.01	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	5/11/2020
	Loss on Drying	1.0% maximum	0.0449	0.0183	0.0162	0.0150	0.0069	0.0322	0.0086	5/11/2020
2018 Lot 1 2P/P	Absorbance (1M)	Monitor @ 280 nm	0.0000	0.0057	0.0123	0.0113	0.0119	0.0104	3/27/2020	3/26/2021
		Monitor @ 260 nm	0.0003	0.0098	0.0143	0.0162	0.0174	0.0151	3/27/2020	3/26/2021
	Assay	98.0-100.5%	98.7	100.1	99.9	98.6	98.5	100.3	3/27/2020	3/26/2021
	Limit of Chlorine	0.6% maximum	<0.01	0.01	<0.01	<0.01	<0.01	<0.01	3/27/2020	3/26/2021
	Loss on Drying	1.0% maximum	0.0622	0.0660	0.1393	0.0456	<0.0075	0.0235	3/27/2020	3/26/2021

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Accelerated Stability Data**Table 3: Tabulated Summary of Accelerated Stability Data**

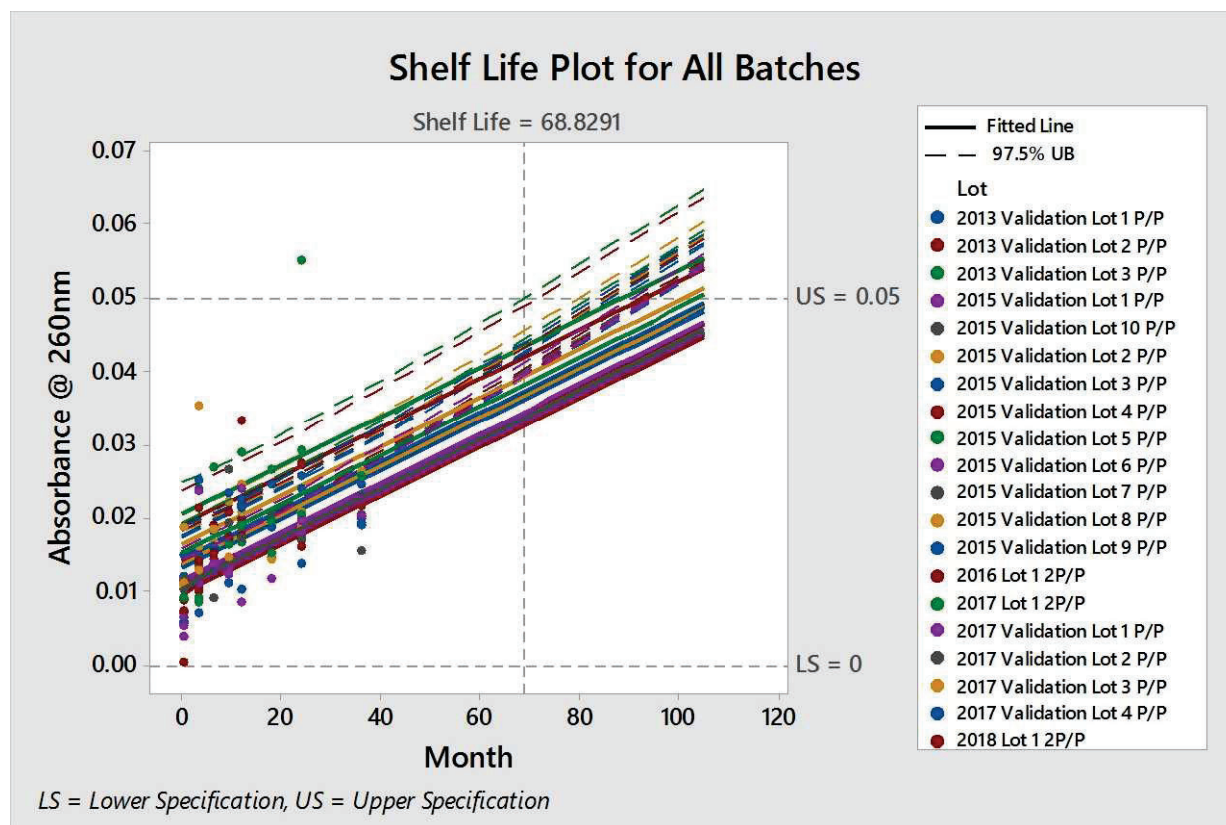
Lot & Sample Designation	Analysis	Specification	T ₀	T ₁	T ₂	T ₃	T ₄	T ₅	T ₆
2013 Validation Lot 1 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0082	0.0214	0.0186	0.0144	0.0007	0.0121	0.0111
		Monitor @ 260 nm	0.0119	0.0266	0.0234	0.0189	0.0044	0.0165	0.0154
	Assay	98.0-100.5%	98.9	98.7	99.7	99.1	99.6	100.0	100.0
	Limit of Chlorine	0.6% maximum	0.02	0.01	0.01	0.02	0.03	0.01	0.01
	Loss on Drying	1.0% maximum	0.0079	0.0197	0.0187	0.0124	0.0124	0.0238	0.0025
2013 Validation Lot 2 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0085	0.0220	0.0198	0.0200	0.0075	0.0127	0.0153
		Monitor @ 260 nm	0.0114	0.0264	0.0240	0.0242	0.0114	0.0162	0.0194
	Assay	98.0-100.5%	98.8	98.3	99.2	98.7	99.1	100.2	99.8
	Limit of Chlorine	0.6% maximum	0.18	0.01	0.01	0.03	0.02	0.01	0.01
	Loss on Drying	1.0% maximum	0.0427	0.0245	0.0134	0.0197	0.0270	0.0249	0.0244
2013 Validation Lot 3 P/P	Absorbance (1M)	Monitor @ 280 nm	0.0060	0.0190	0.0184	0.0167	0.0069	0.0129	0.0123
		Monitor @ 260 nm	0.0090	0.0237	0.0229	0.0215	0.0113	0.0174	0.0167
	Assay	98.0-100.5%	99.2	98.1	99.6	98.5	99.6	100.2	99.8
	Limit of Chlorine	0.6% maximum	0.04	0.03	0.02	0.02	0.04	0.02	0.00
	Loss on Drying	1.0% maximum	<0.0050	0.0179	0.0092	0.0323	0.0297	0.0193	0.0243

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Long-Term Stability Graphs**Graph 1: Absorbance (1M) @ 280 nm All Packaging Types**

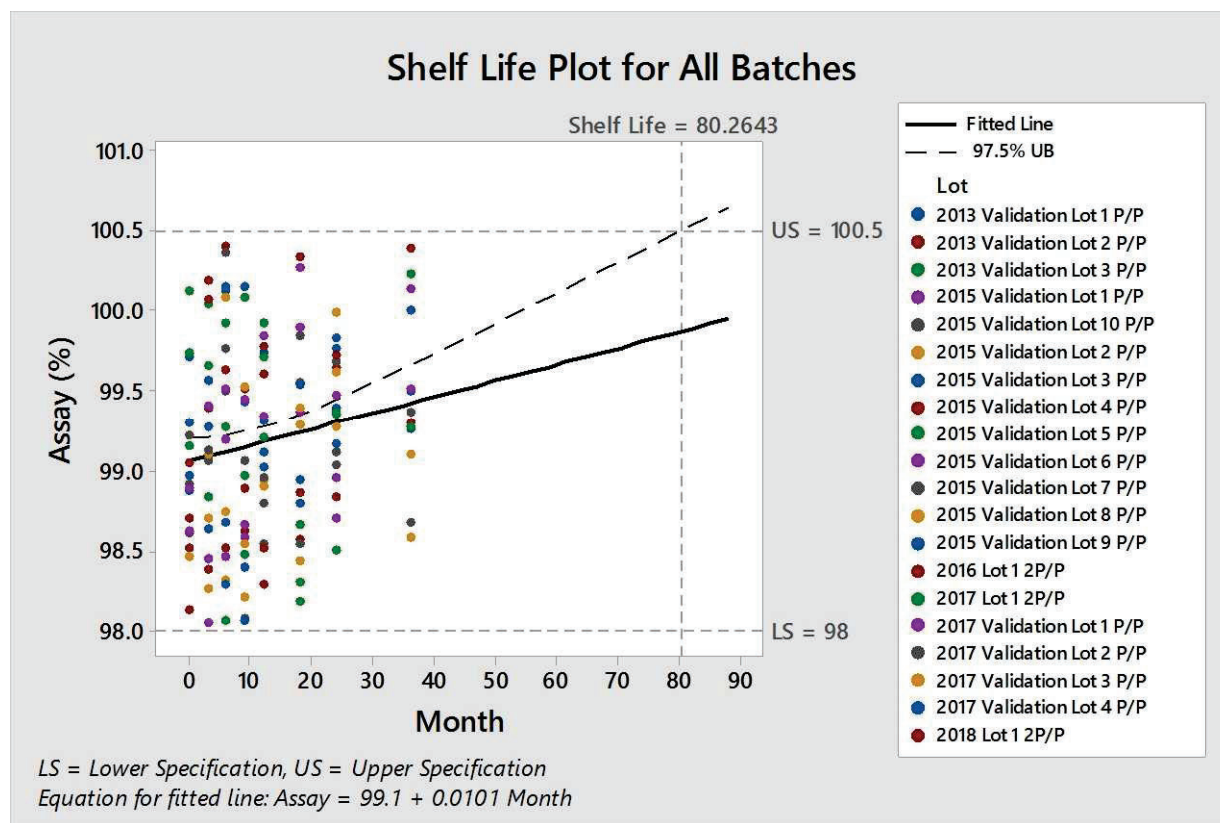
A shelf life of 99.0261 months was predicted for absorbance @ 280nm, which is well above the current retest date of 24 months.

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Graph 2: Absorbance (1M) @ 260 nm All Packaging Types

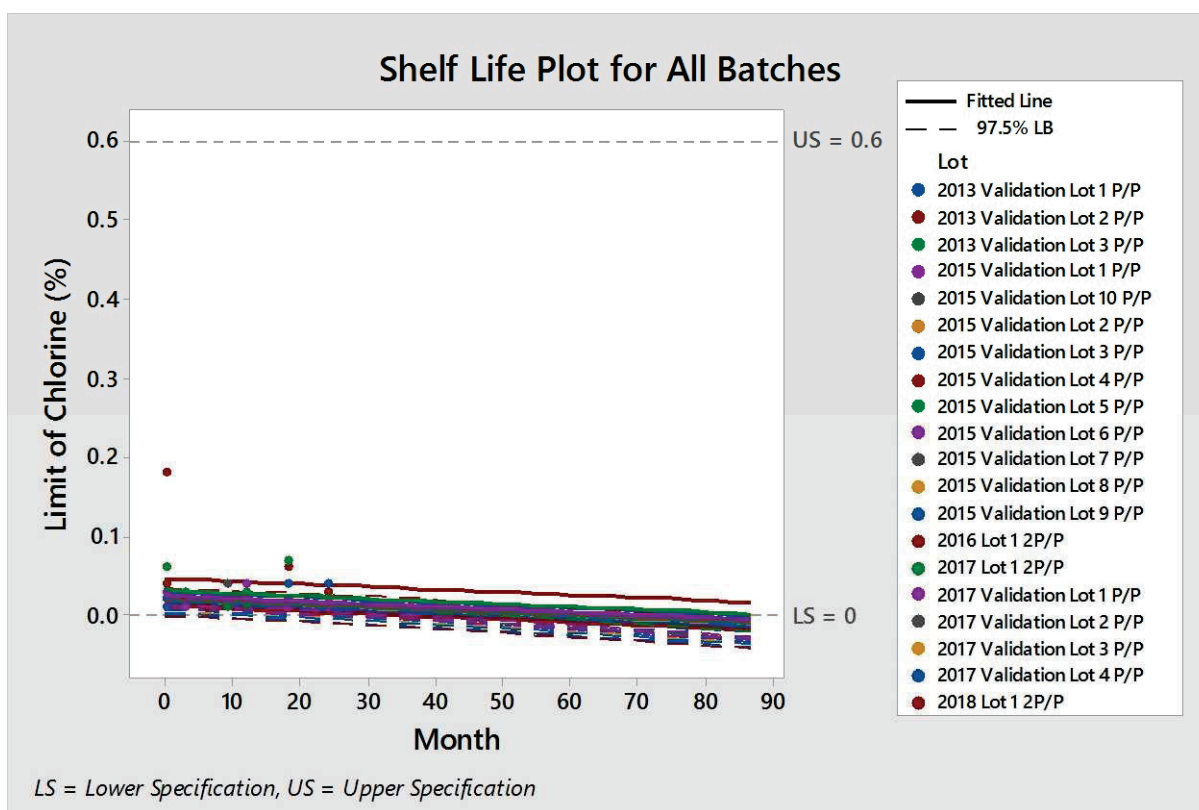
A shelf life of 68.8291 months was predicted for absorbance @ 260nm, which is well above the current retest date of 24 months.

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Graph 3: Assay (%) All Packaging Types

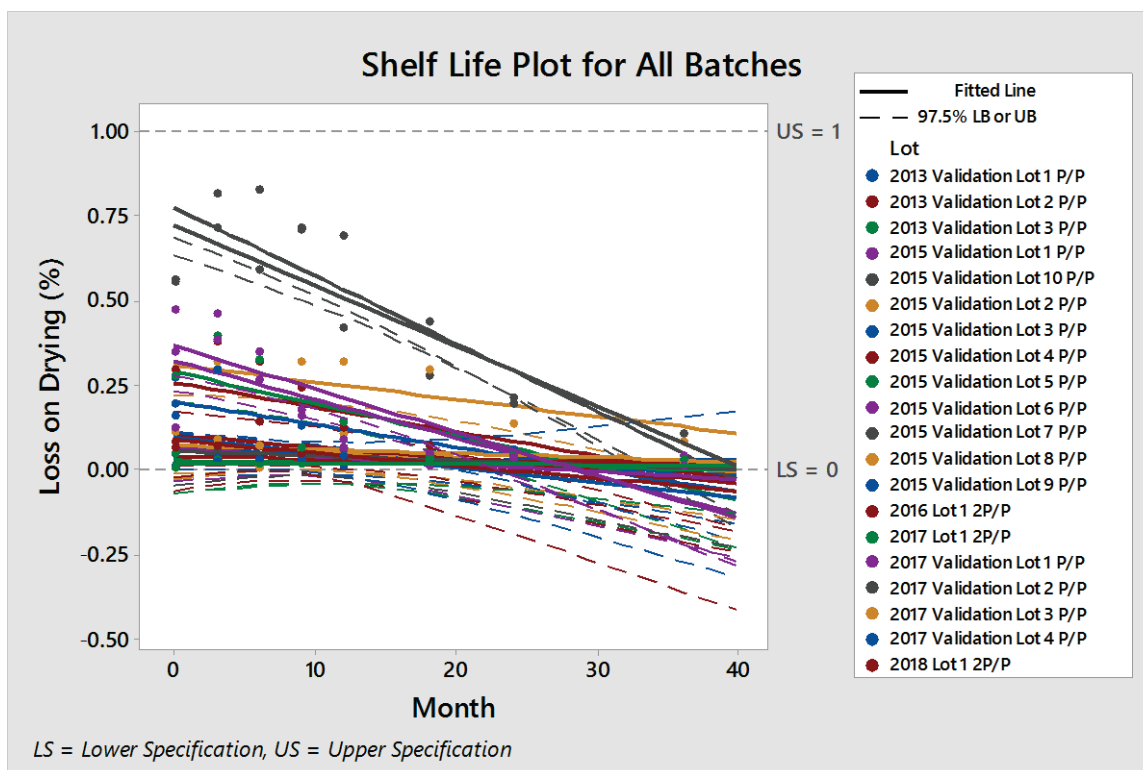
A shelf life of 80.2643 months was predicted for assay, which is well above the current retest date of 24 months.

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Graph 4: Limit of Chlorine (%) All Packaging Types

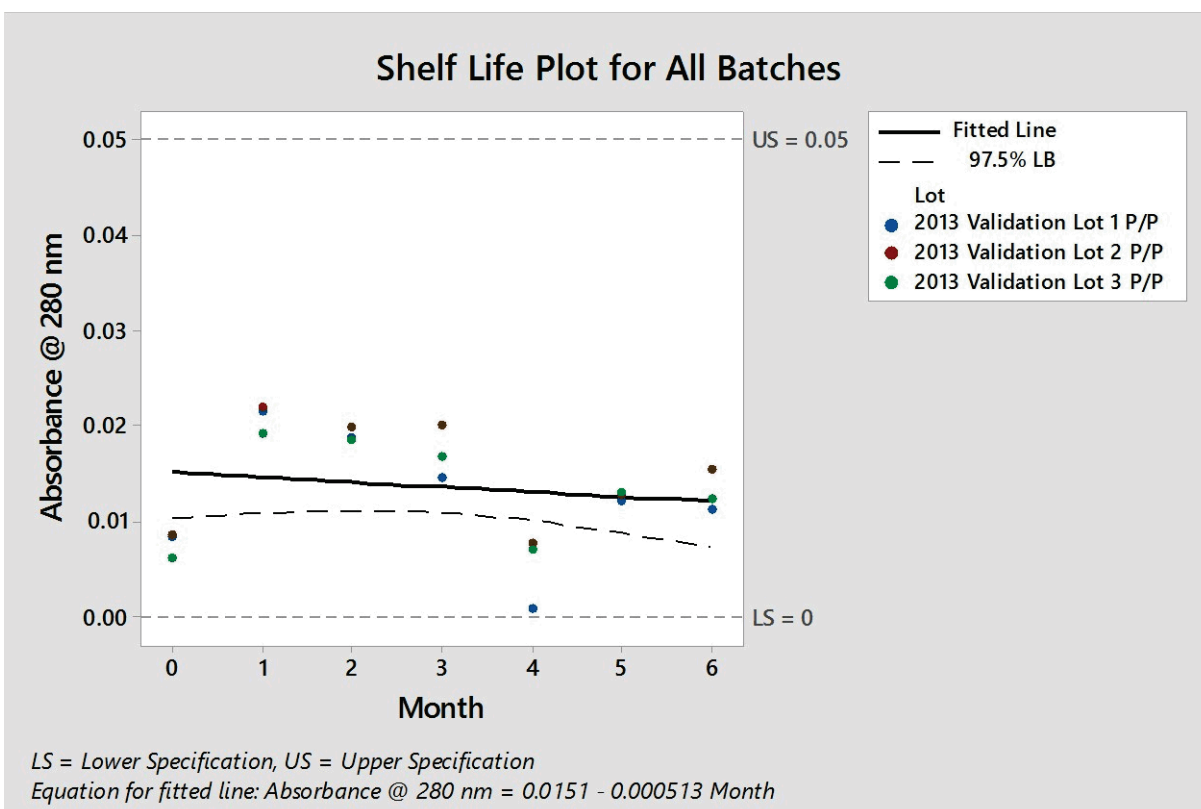
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

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Graph 5: Loss on Drying (%) All Packaging Types

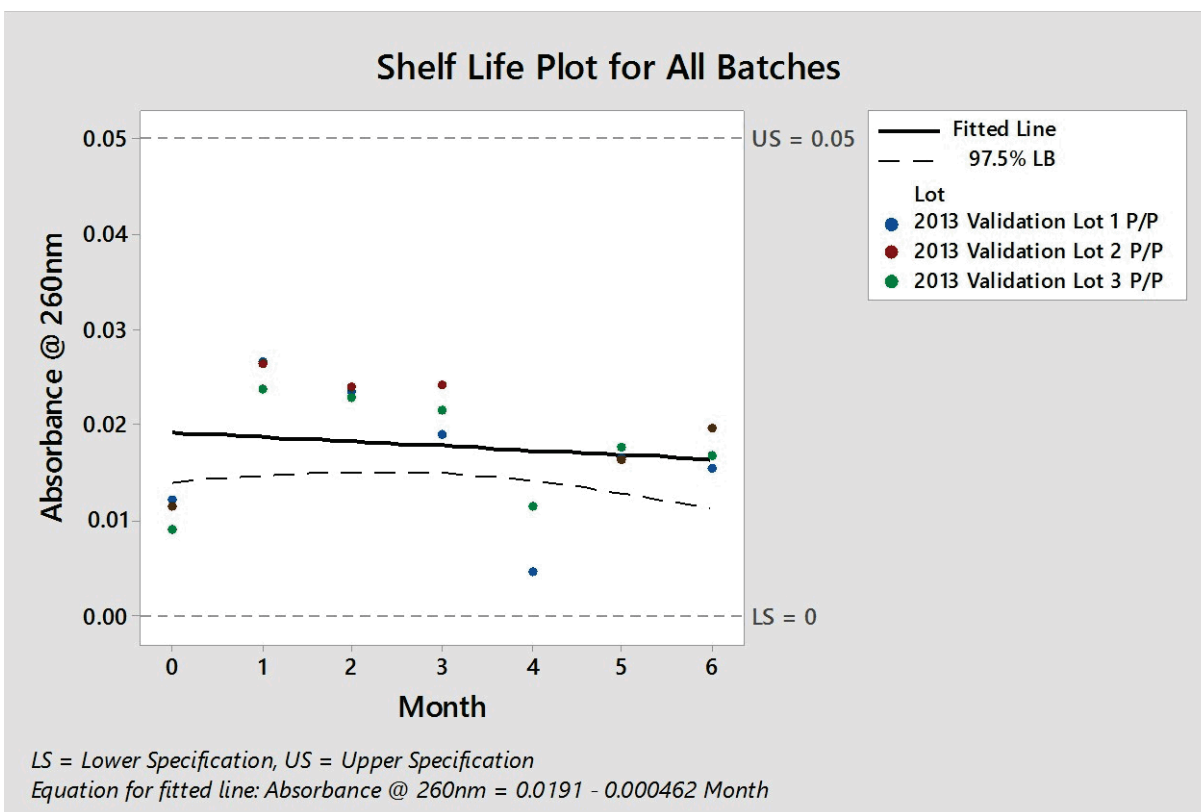
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

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Accelerated Stability Graphs**Graph 6: Absorbance (1M) @ 280 nm All Packaging Types**

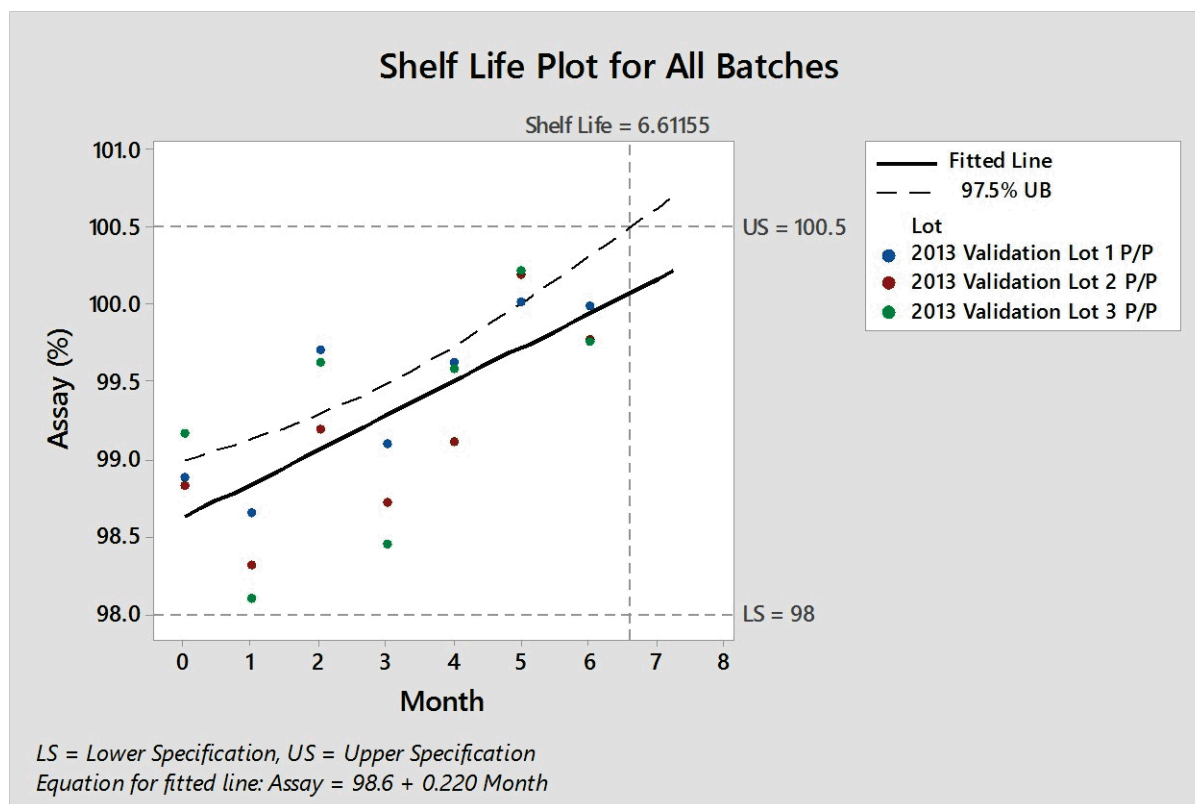
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

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Graph 7: Absorbance (1M) @ 260 nm All Packaging Types

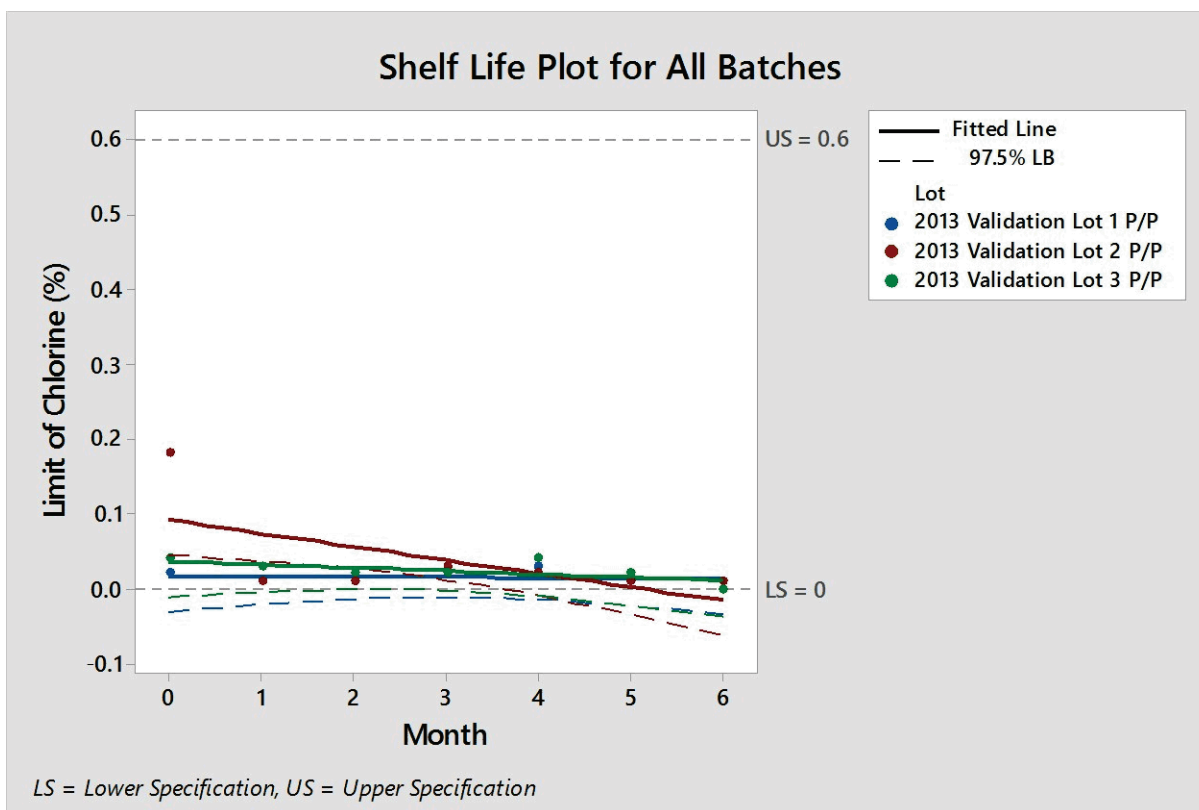
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

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Graph 8: Assay (%) All Packaging Types

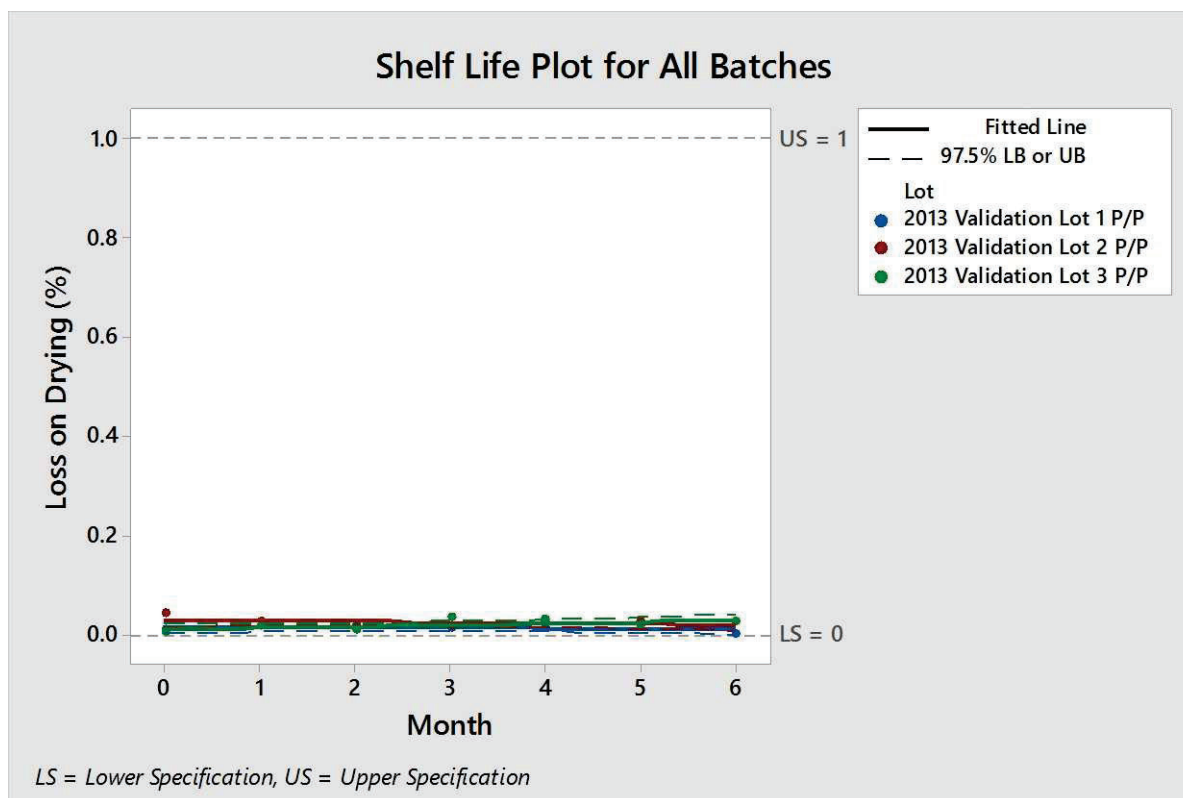
A shelf life of 6.61155 months was predicted for assay. This shelf life is not a concern, as additional long-term stability data has been collected and shown Potassium Bromide Assay (%) to be stable well over the reported two-year retest date with an estimated shelf life of 80.2643 months.

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Graph 9: Limit of Chlorine (%) All Packaging Types

The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

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Graph 10: Loss on Drying (%) All Packaging Types

The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

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