



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

HEPES 2021 VALIDATION LOTS 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 HEPES Bio Excipient material lot manufactured in 2021 at the Rockdale facility in Stroudsburg, PA. Testing intervals are designated by T_n, where n equals 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 HEPES Bio Excipient material validation lots HEPE-0221-00009-PV, HEPE-0221-00010-PV, HEPE-0221-00015-PV and HEPE-0221-00126-PV that completed thirty-six (36) months of long-term stability in September 2024. This study includes the following analyses: Absorbance (0.1M) at 280 nm, 260 nm, and 250 nm, Appearance and Color, Assay (Dried), Loss on Drying, and pH (5%). Results from all analyses are summarized in Table 2 through Table 9. 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 for HEPES. The following product codes are commercially available.

- HEPE-3220
- HEPE-3221
- HEPE-3250
- HEPE-3251
- HEPE-4220

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. The samples placed on the Stability Testing Program consisted of four validation lots of HEPES Bio Excipient material. Stability samples from this lot were put Poly/Poly and Labline packaging configurations. The samples were packaged in accordance with the Stability Inventory Procedure. Reference Table 1 for packaging configuration and description. The type of packaging utilized in this stability study was based on BioSpectra's packaging configurations offered to the customer.

TABLE 1: PACKAGING DETAILS

Packaging Configurations	Description of Packaging Configurations
Poly/Poly (P/P)	Samples are individually placed into small polybags and are sealed with a zip tie. All individual bags are then placed into a poly pail and sealed.
Lab Screw-Top Bottle (Labline)	Samples are individually placed into small labscrew-top bottles and sealed with a tamper-evident lid.

4. STORAGE

The Packaging and storage requirements for HEPES Bio Excipient material are to be in tightly closed container in a dry and well-ventilated place. For this study, samples were stored in the Long-Term Stability Chamber H03SC01 at the Bangor, PA facility. 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 ($60\% \pm 5$). For the time period of April 2021 to December 2023 the samples were located in the Long-Term Stability Chamber H03SC01. The maximum temperature recorded was 26.31°C , the minimum temperature was 22.63°C , the average temperature was 25.45°C , and the Average Mean Kinetic Temperature was 25.45°C . The maximum relative humidity recorded was 80.5%, the minimum relative humidity was 31.1%, and the average relative humidity was 61.4%. In December 2023 the stability samples were moved under BTOI23-213 / BCC23-71. The samples were moved from H03SC01 (existing qualified Long-Term chamber) to H02SC01 (newly qualified Long-Term chamber) until present day. The maximum temperature recorded was 25.65°C , the minimum temperature was 24.82°C , the average temperature was 25.10°C , and the Average Mean Kinetic Temperature was 25.10°C . The maximum relative humidity recorded was 74.3%, the minimum relative humidity was 55.0%, and the average relative humidity was 57.8%. 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. **BDI22-61:** This discrepancy documents missing data points from the download of the MadgeTech temperature loggers between 1/28/22 and 2/09/22. The logger was reset and started to work. No known reason could be identified as to why the logger stopped recording. There was no impact to the stability samples being stored in the chamber as the analog chart recorders showed no temperature deviations.
- 5.2. **BDI22-138:** This discrepancy documents an out of specification humidity reading of 50.8% that lasted for over 4 hours. This was due to a valve that regulates humidity being turned off. There was no impact to the stability samples because the excursion was brief and lasted less than 5 hours.
- 5.3. **BDI22-143:** This discrepancy investigation documents observed deviations in the Real Time Stability Chamber in November 2021 for missing data points. The root cause was identified to be expired batteries in the MadgeTech temperature loggers. There was no impact to the stability samples being stored in the chamber as the analog chart recorders showed no temperature deviations.
- 5.4. **BDI24-13:** Out of range humidity for the Real Time Stability Chamber H03SC01 occurred and was found to be 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 was later repaired. There was no impact to the current list of materials in the stability chamber
- 5.5. **BDI24-126:** Out of specification humidity and temperature for H03SC01 occurred on 8/15/24 with a humidity reading of 54.4% and a temperature of 21.81°C. It was discovered that a 20-amp fuse had blown. The fuse was replaced and the chamber went back into specification on 8/16/24 with a humidity reading of 62.3%. There was no impact on the stability samples as this excursion lasted less than 24 hours.

6. LOT EVALUATION:

TABLE 2: HEPE-0221-00009-PV P/P

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0015 a.u.	0.0016 a.u.	0.0021 a.u.	0.0028 a.u.	0.0048 a.u.	0.0075 a.u.	0.0019 a.u.	0.0036 a.u.
	≤0.050 a.u. @ 260 nm	0.0024 a.u.	0.0023 a.u.	0.0028 a.u.	0.0037 a.u.	0.0066 a.u.	0.0093 a.u.	0.0027 a.u.	0.0042 a.u.
	≤0.050 a.u. @ 250 nm	0.0066 a.u.	0.0065 a.u.	0.0073 a.u.	0.0080 a.u.	0.0118 a.u.	0.0144 a.u.	0.0068 a.u.	0.0085 a.u.
Appearance and Color	White/Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals
Assay	≥99.0%	100.38%	100.28%	100.33%	100.36%	100.20%	100.43%	100.09%	100.46%
pH (5%)	5.0-6.5	5.27	5.29	5.34	5.34	5.25	5.28	5.28	5.28
Loss on Drying	≤0.5%	<0.0150%	<0.0167%	<0.0164%	<0.0155%	0.0240%	0.0186%	0.0745%	0.0652%

- REMAINING TESTING INTERVAL PULL DATES

- T = 48; Scheduled for April 26, 2025
- T = 60; Scheduled for April 26, 2026

TABLE 3: HEPE-0221-00009-PV LABLINE

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0015 a.u.	0.0009 a.u.	0.0014 a.u.	0.0018 a.u.	0.0017 a.u.	0.0014 a.u.	0.0011 a.u.	0.0021 a.u.
	≤0.050 a.u. @ 260 nm	0.0024 a.u.	0.0016 a.u.	0.0022 a.u.	0.0025 a.u.	0.0034 a.u.	0.0022 a.u.	0.0017 a.u.	0.0030 a.u.
	≤0.050 a.u. @ 250 nm	0.0066 a.u.	0.0059 a.u.	0.0068 a.u.	0.0067 a.u.	0.0085 a.u.	0.0064 a.u.	0.0055 a.u.	0.0070 a.u.
Appearance and Color	White/Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals
Assay	≥99.0%	100.38%	100.36%	99.83%	100.39%	100.32%	100.03%	100.29%	100.37%
pH (5%)	5.0-6.5	5.27	5.28	5.30	5.26	5.23	5.29	5.27	5.31
Loss on Drying	≤0.5%	<0.0150%	<0.0188%	0.1147%	<0.0152%	0.0325%	0.0266%	0.0520%	0.0746%

- REMAINING TESTING INTERVAL PULL DATES

- T = 48; Scheduled for April 26, 2025
- T = 60; Scheduled for April 26, 2026

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TABLE 4: HEPE-0221-00010-PV P/P

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0021 a.u.	0.0015 a.u.	0.0031 a.u.	0.0026 a.u.	0.0020 a.u.	0.0029 a.u.	0.0034 a.u.	0.0034 a.u.
	≤0.050 a.u. @ 260 nm	0.0026 a.u.	0.0020 a.u.	0.0041 a.u.	0.0034 a.u.	0.0029 a.u.	0.0035 a.u.	0.0042 a.u.	0.0043 a.u.
	≤0.050 a.u. @ 250 nm	0.0064 a.u.	0.0056 a.u.	0.0082 a.u.	0.0079 a.u.	0.0072 a.u.	0.0079 a.u.	0.0085 a.u.	0.0088 a.u.
Appearance and Color	White/Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals
Assay	≥99.0%	100.39%	100.13%	100.09%	100.23%	100.12%	100.28%	100.35%	100.42%
pH (5%)	5.0-6.5	5.22	5.25	5.24	5.30	5.30	5.26	5.31	5.31
Loss on Drying	≤0.5%	0.0368%	0.0324%	<0.0160%	0.0675%	0.0208%	0.0398%	0.0768%	0.0197%

- **REMAINING TESTING INTERVAL PULL DATES**

- T = 48; Scheduled for June 3, 2025
- T = 60; Scheduled for June 3, 2026

TABLE 5: HEPE-0221-00010-PV LABLINE

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0021 a.u.	0.0017 a.u.	0.0019 a.u.	0.0018 a.u.	0.0015 a.u.	0.0019 a.u.	0.0022 a.u.	0.0021 a.u.
	≤0.050 a.u. @ 260 nm	0.0026 a.u.	0.0023 a.u.	0.0026 a.u.	0.0025 a.u.	0.0023 a.u.	0.0031 a.u.	0.0029 a.u.	0.0030 a.u.
	≤0.050 a.u. @ 250 nm	0.0064 a.u.	0.0059 a.u.	0.0066 a.u.	0.0068 a.u.	0.0066 a.u.	0.0071 a.u.	0.0074 a.u.	0.0073 a.u.
Appearance and Color	White/Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals
Assay	≥99.0%	100.39%	100.12%	100.10%	100.44%	100.03 %	100.45%	100.34%	99.95%
pH (5%)	5.0-6.5	5.22	5.23	5.23	5.28	5.30	5.26	5.30	5.28
Loss on Drying	≤0.5%	0.0368%	<0.0122%	<0.0089%	0.0292%	0.0347%	0.0330%	0.0430%	0.0362%

- **REMAINING TESTING INTERVAL PULL DATES**

- T = 48; Scheduled for June 3, 2025
- T = 60; Scheduled for June 3, 2026

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TABLE 6: HEPE-0221-00015-PV P/P

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0021 a.u.	0.0025 a.u.	0.0032 a.u.	0.0046 a.u.	0.0030 a.u.	0.0042 a.u.	0.0041 a.u.	0.0041 a.u.
	≤0.050 a.u. @ 260 nm	0.0025 a.u.	0.0030 a.u.	0.0040 a.u.	0.0070 a.u.	0.0042 a.u.	0.0051 a.u.	0.0049 a.u.	0.0049 a.u.
	≤0.050 a.u. @ 250 nm	0.0059 a.u.	0.0066 a.u.	0.0083 a.u.	0.0113 a.u.	0.0086 a.u.	0.0097 a.u.	0.0097 a.u.	0.0094 a.u.
Appearance and Color	White/Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals
Assay	≥99.0%	100.35%	100.33%	100.22%	100.21%	100.21%	100.31%	100.38%	100.29%
pH (5%)	5.0-6.5	5.24	5.25	5.24	5.43	5.30	5.28	5.30	5.29
Loss on Drying	≤0.5%	0.0553%	0.0253%	<0.0098%	0.0208%	0.0672%	0.0520%	0.0503%	0.0168%

- **REMAINING TESTING INTERVAL PULL DATES**

- T = 48; Scheduled for June 3, 2025
- T = 60; Scheduled for June 3, 2026

TABLE 7: HEPE-0221-00015-PV LABLINE

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0021 a.u.	0.0020 a.u.	0.0025 a.u.	0.0033 a.u.	0.0029 a.u.	0.0027 a.u.	0.0030 a.u.	0.0039 a.u.
	≤0.050 a.u. @ 260 nm	0.0025 a.u.	0.0025 a.u.	0.0031 a.u.	0.0044 a.u.	0.0043 a.u.	0.0036 a.u.	0.0039 a.u.	0.0049 a.u.
	≤0.050 a.u. @ 250 nm	0.0059 a.u.	0.0061 a.u.	0.0073 a.u.	0.0087 a.u.	0.0085 a.u.	0.0080 a.u.	0.0085 a.u.	0.0093 a.u.
Appearance and Color	White/Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals	White/ Crystals
Assay	≥99.0%	100.35%	100.14%	100.29%	100.21%	100.17%	100.42%	100.30%	100.23%
pH (5%)	5.0-6.5	5.24	5.26	5.23	5.39	5.29	5.27	5.31	5.29
Loss on Drying	≤0.5%	0.0553%	<0.0126%	<0.0174%	0.0529%	0.0431%	0.0346%	<0.0114%	0.0265%

- **REMAINING TESTING INTERVAL PULL DATES**

- T = 48; Scheduled for June 3, 2025
- T = 60; Scheduled for June 3, 2026

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TABLE 8: HEPE-0221-00126-PV P/P

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0053 a.u.	0.0052 a.u.	0.0057 a.u.	0.0046 a.u.	0.0071 a.u.	0.0080 a.u.	0.0113 a.u.	0.0091 a.u.
	≤0.050 a.u. @ 260 nm	0.0058 a.u.	0.0056 a.u.	0.0065 a.u.	0.0048 a.u.	0.0076 a.u.	0.0090 a.u.	0.0125 a.u.	0.0102 a.u.
	≤0.050 a.u. @ 250 nm	0.0100 a.u.	0.0103 a.u.	0.0114 a.u.	0.0092 a.u.	0.0127 a.u.	0.0137 a.u.	0.0188 a.u.	0.0157 a.u.
Appearance and Color	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals
Assay	≥99.0%	100.43%	100.10%	100.13%	100.33%	100.40%	100.16%	100.63%	100.78%
pH (5%)	5.0-6.5	5.41	5.34	5.26	5.30	5.34	5.31	5.30	5.28
Loss on Drying	≤0.5%	0.0835%	0.0281%	0.0179%	0.0697%	0.0796%	0.0669%	0.0638%	<0.0099%

- **REMAINING TESTING INTERVAL PULL DATES**

- T = 48; Scheduled for September 10, 2025
- T = 60; Scheduled for September 10, 2026

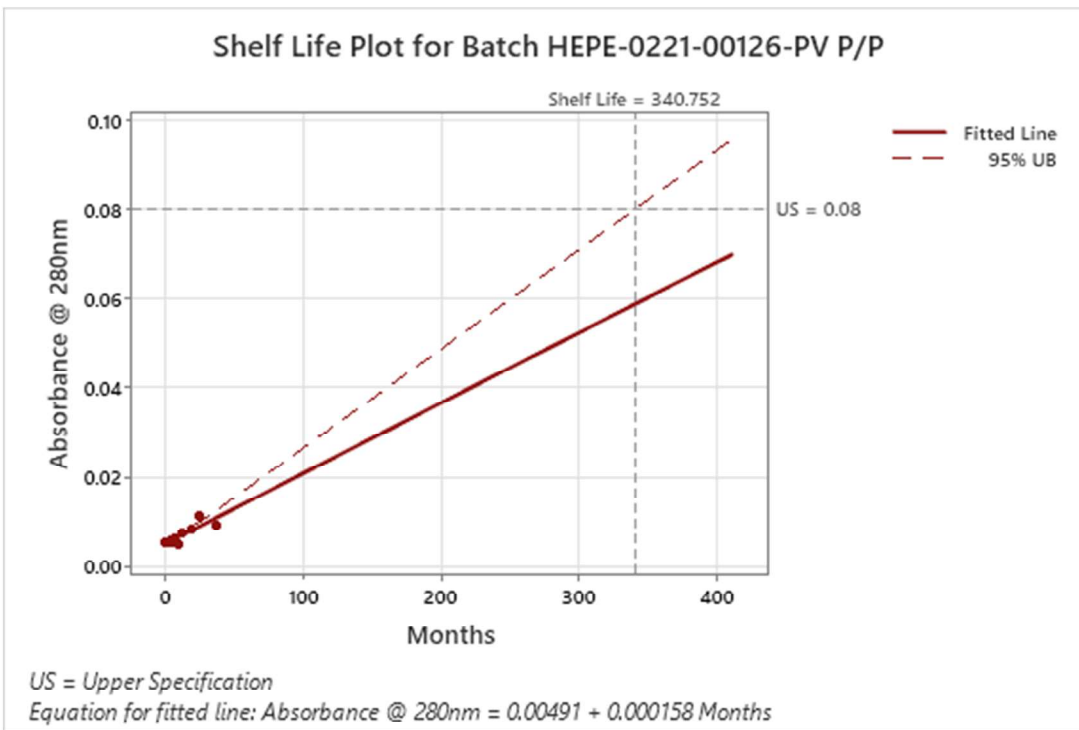
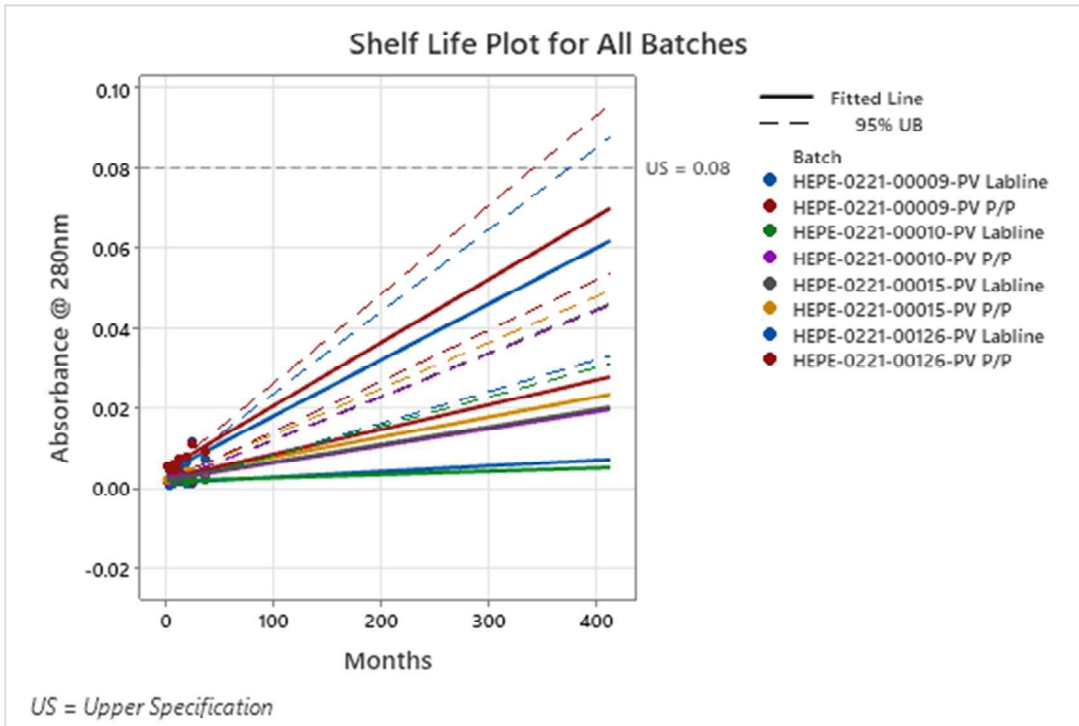
TABLE 9: HEPE-0221-00126-PV LABLINE

Analysis	Specification	T ₀	T ₃	T ₆	T ₉	T ₁₂	T ₁₈	T ₂₄	T ₃₆
Absorbance (0.1M)	≤0.080 a.u. @ 280 nm	0.0053 a.u.	0.0045 a.u.	0.0050 a.u.	0.0034 a.u.	0.0045 a.u.	0.0062 a.u.	0.0117 a.u.	0.0075 a.u.
	≤0.050 a.u. @ 260 nm	0.0058 a.u.	0.0050 a.u.	0.0058 a.u.	0.0038 a.u.	0.0047 a.u.	0.0070 a.u.	0.0130 a.u.	0.0088 a.u.
	≤0.050 a.u. @ 250 nm	0.0100 a.u.	0.0098 a.u.	0.0106 a.u.	0.0082 a.u.	0.0091 a.u.	0.0114 a.u.	0.0192 a.u.	0.0142 a.u.
Appearance and Color	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals	White/Crystals
Assay	≥99.0%	100.43%	100.34%	100.29%	100.50%	100.41%	100.09%	100.56%	100.68%
pH (5%)	5.0-6.5	5.41	5.33	5.40	5.27	5.33	5.28	5.29	5.28
Loss on Drying	≤0.5%	0.0835%	<0.0147%	<0.0143%	0.0444%	0.0744%	0.0356%	0.0709%	<0.0089%

- **REMAINING TESTING INTERVAL PULL DATES**

- T = 48; Scheduled for September 10, 2025
- T = 60; Scheduled for September 10, 2026

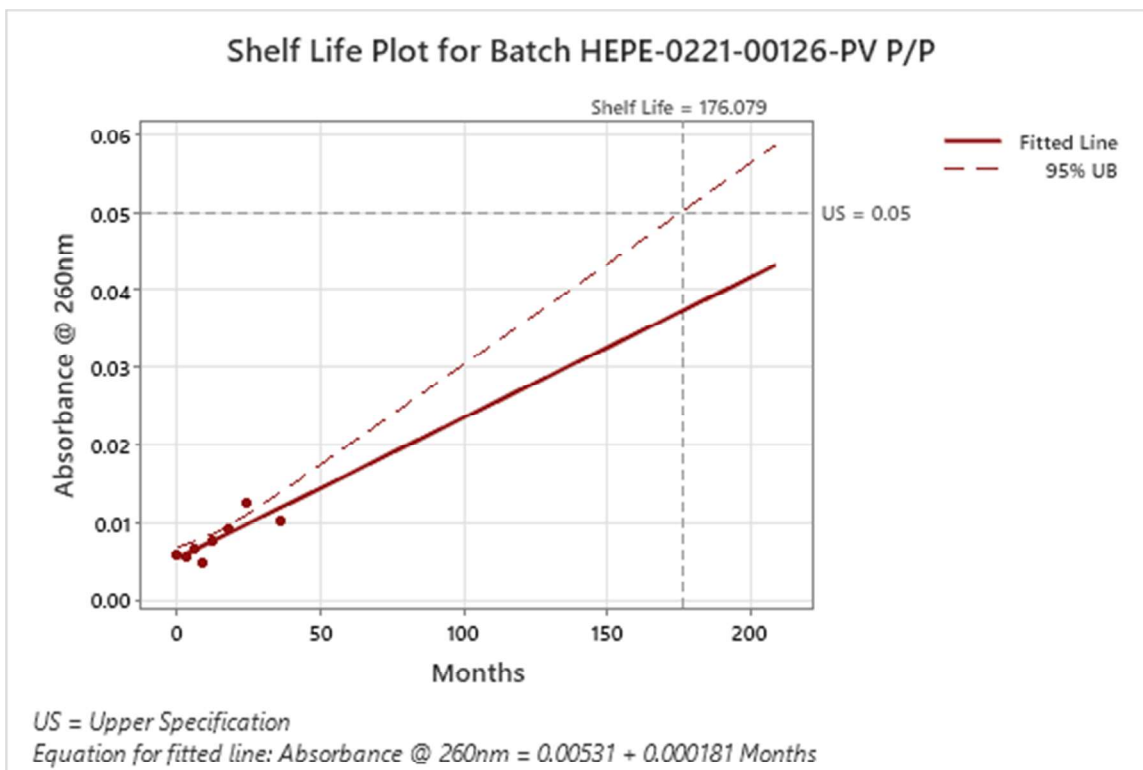
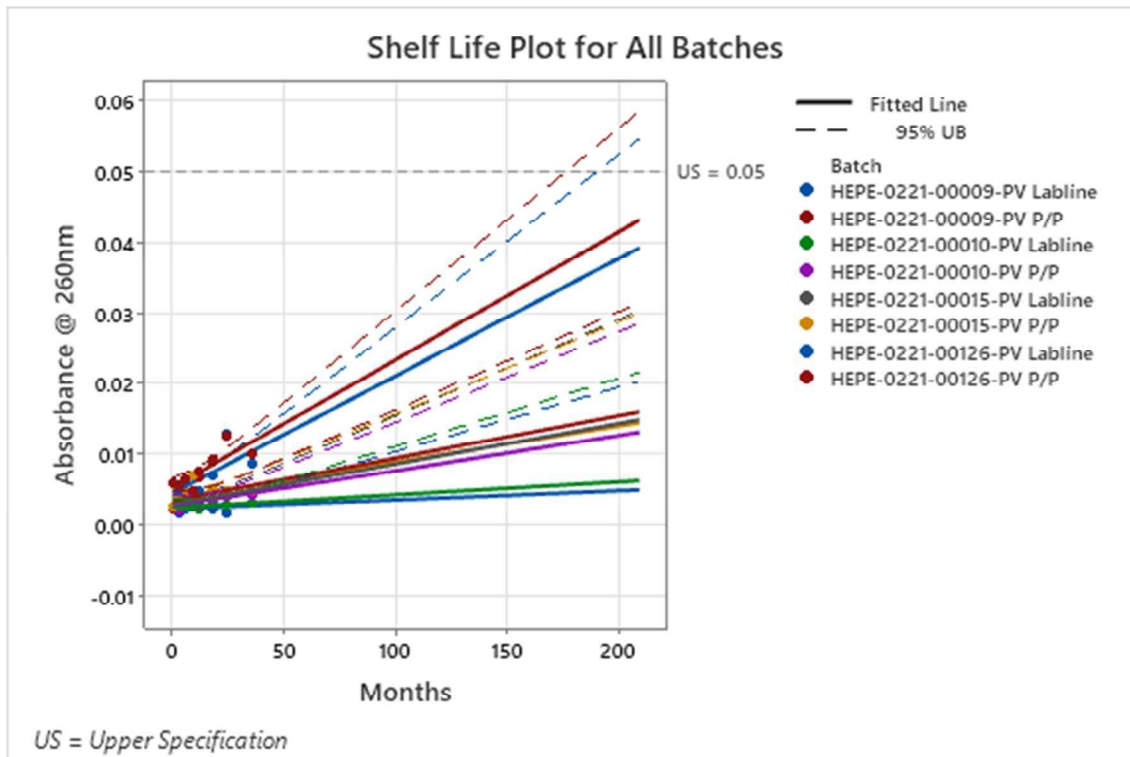
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GRAPH 1: ABSORBANCE @ 280 NM

The predicted Shelf-Life for Absorbance @ 280 nm was determined to be 340.752 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.

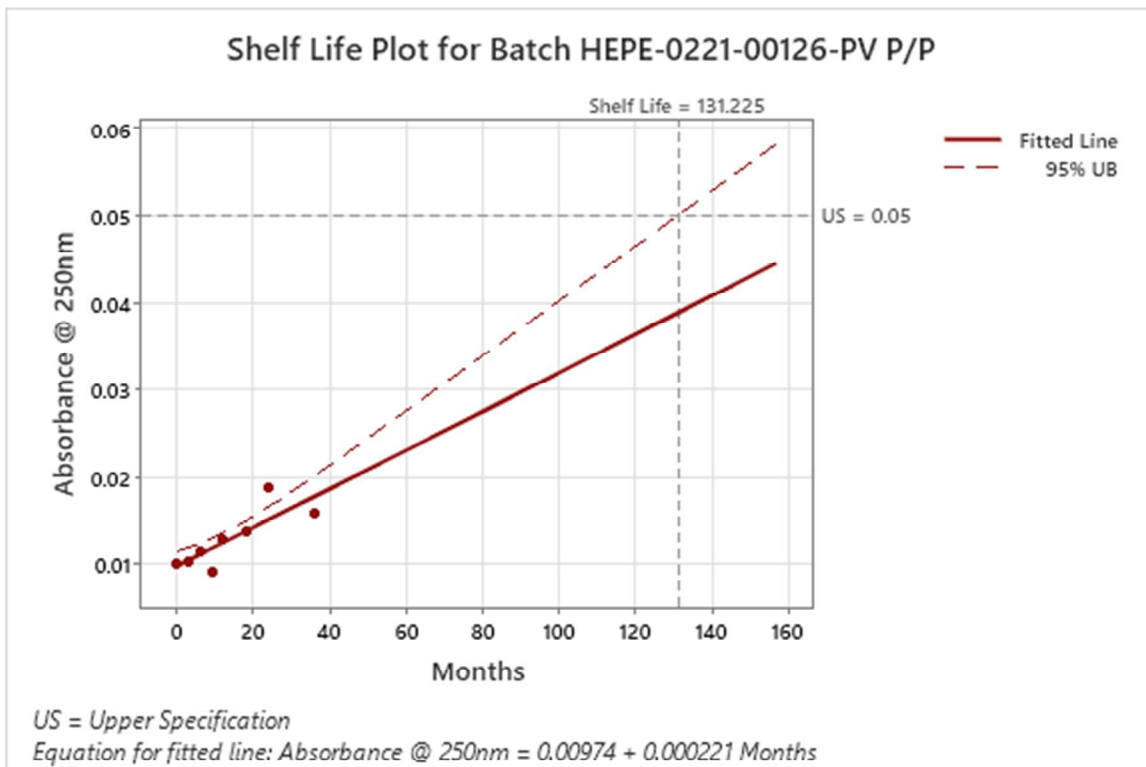
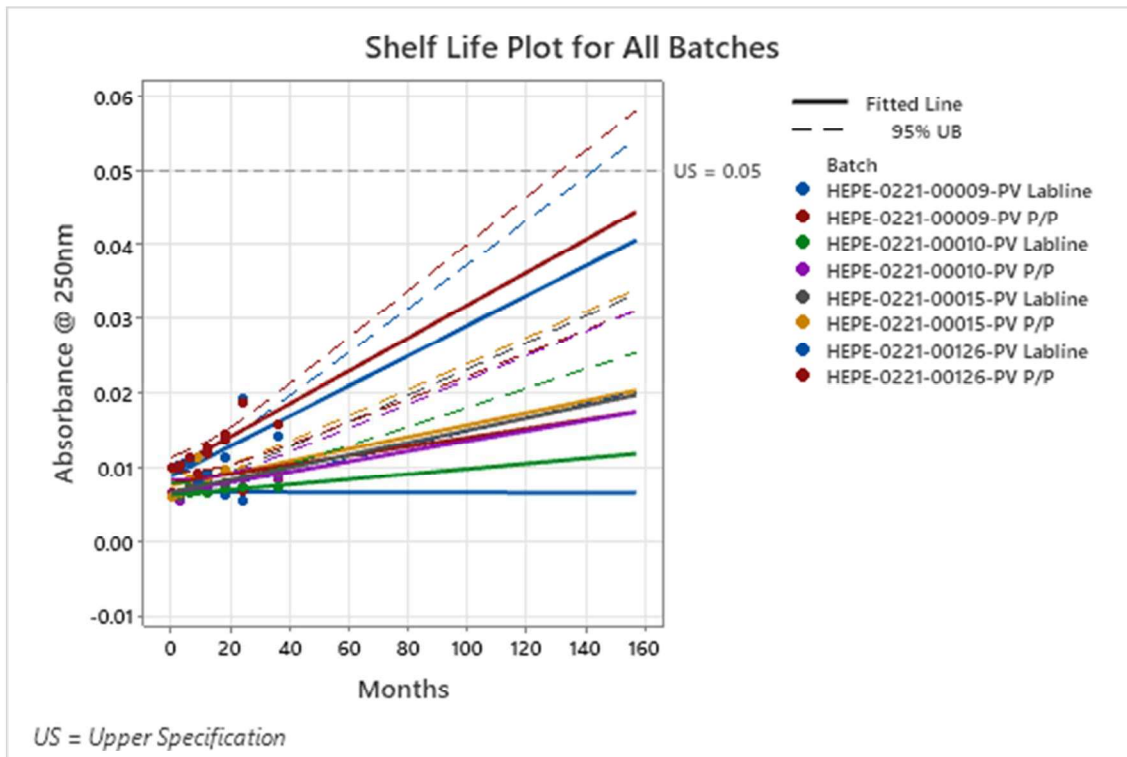
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GRAPH 2: ABSORBANCE @ 260 NM

The predicted Shelf-Life for Absorbance @ 260 nm was determined to be 176.079 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.

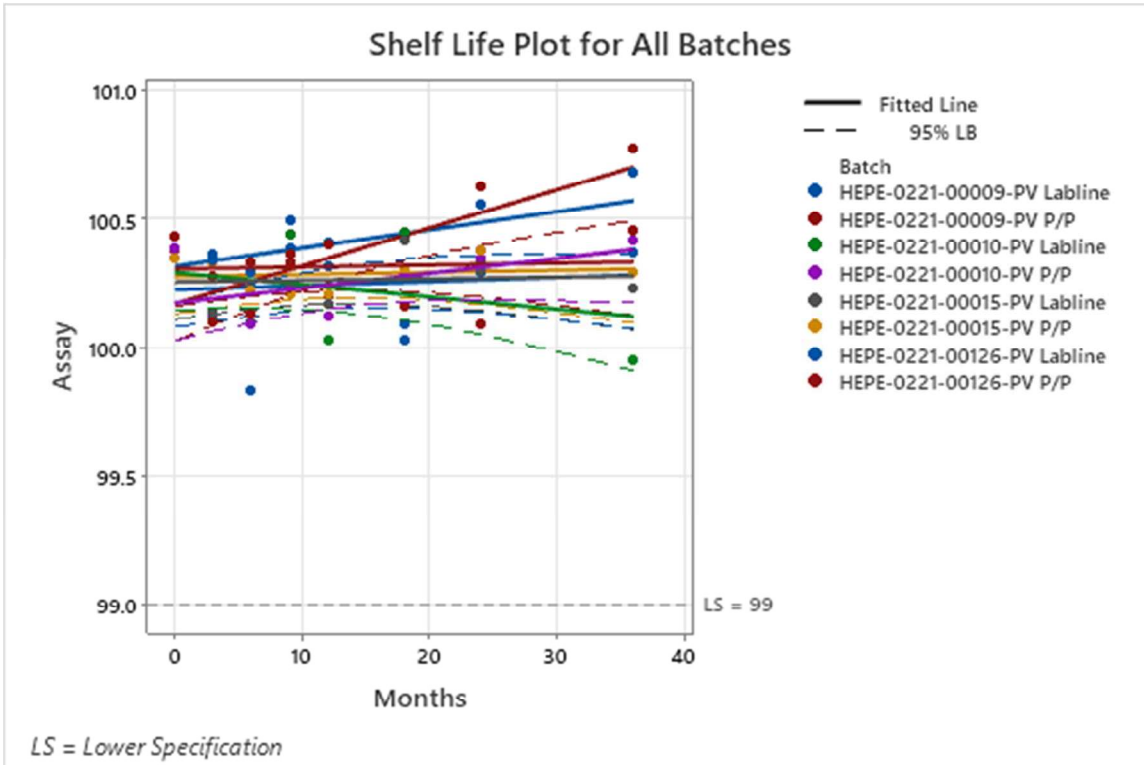
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GRAPH 3: ABSORBANCE @ 250 NM

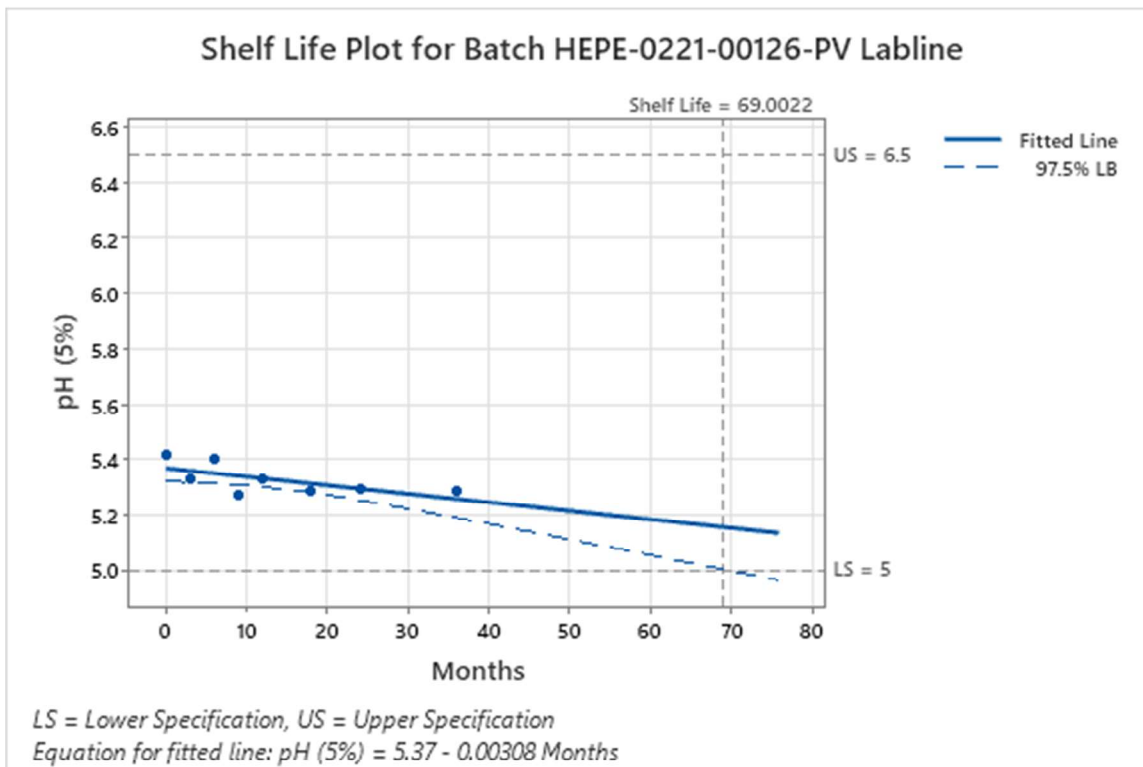
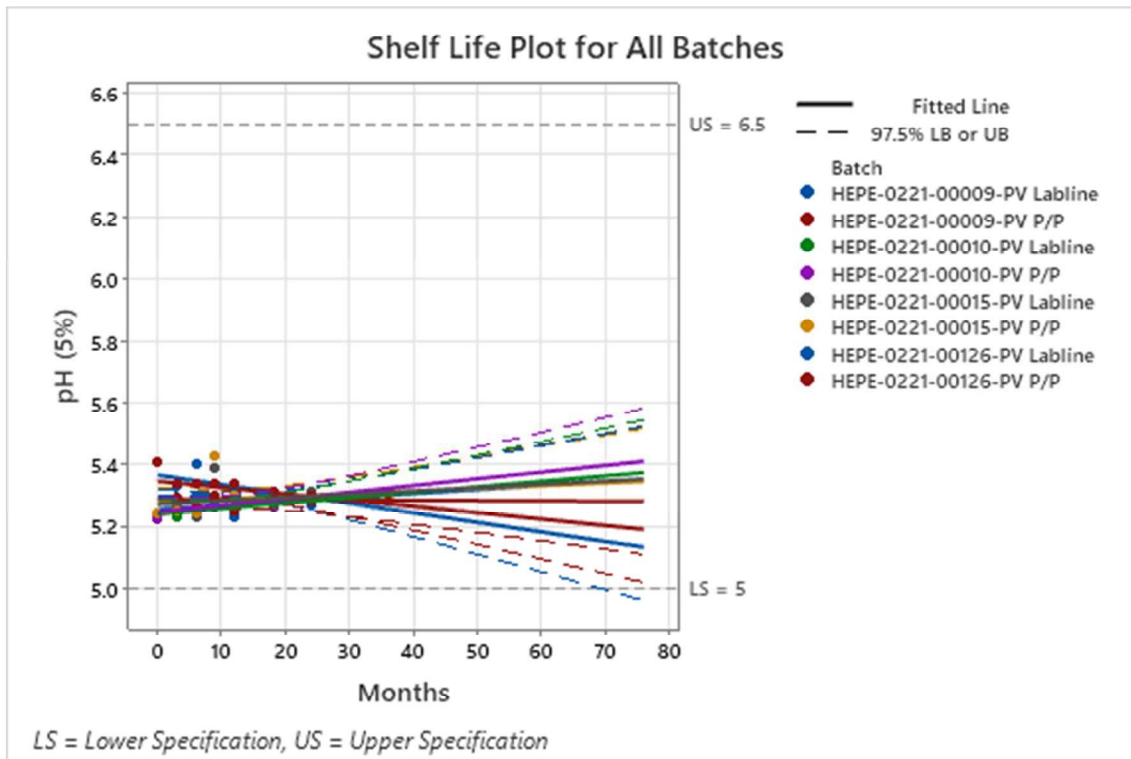
The predicted Shelf-Life for Absorbance @ 250 nm was determined to be 131.225 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.

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GRAPH 4: ASSAY (DRIED)

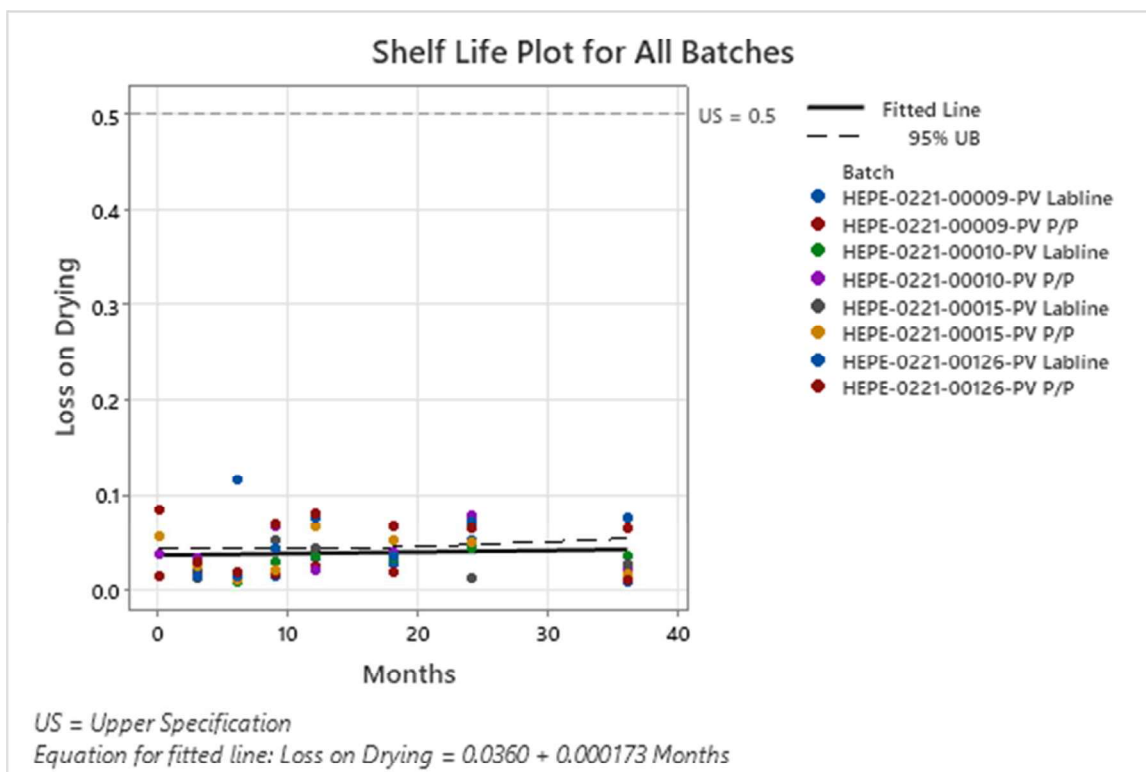
No Shelf-Life was able to be determined for Assay (Dried), as the mean response slope is not significantly different from zero using 95% confidence. There is no impact to the product or currently assigned retest period of this material.



GRAPH 5: PH (5%)

The predicted Shelf-Life for pH (5%) was determined to be 69.0022 months as of the T=36-month time interval. There is no impact to the product or currently assigned retest period of this material.

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GRAPH 6: 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 period of this material.

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 for real time conditions. In regards to the Long-Term Stability Study for HEPES Bio Excipient material, all data met the specifications set forth in the Stability Testing Program for the lot stored at the recommended long-term condition. The Long-Term Stability Study data, along with the predicted shelf-life plots, supports a retest date of 24 months for the 2021 validation lots of HEPES Bio Excipient material, manufactured at BioSpectra in the Rockdale facility in Stroudsburg, PA.

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.