

TREHALOSE, DIHYDRATE
ACCELERATED STABILITY STUDY
2019 VALIDATION LOTS

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1. OVERVIEW:

The purpose of this report is to analyze and conclude on the data obtained from the Accelerated Stability Study of Bio Excipient Grade Trehalose, Dihydrate manufactured at BioSpectra's Bangor, PA facility. Testing intervals are designated by T_n , where n = the number of months on stability. Accelerated testing is performed every month for a period of six months. The analysis of the compiled data may aid in a re-evaluation of the retest date or expiry date for the finished good product.

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 Testing Program. All quantitative data was analyzed using these methods. The data can be found in the Trehalose, Dihydrate Accelerated Stability Program binder.

This Stability Study assesses the stability of four Trehalose, Dihydrate Bio Excipient Grade lots up to the T_6 testing interval. This material was placed on stability on 05/2019 and the T_6 sample was taken in 11/2019. The study included the following analysis: Appearance, Assay, Color and Clarity of Solution, Dextrins, Soluble Starch, and Sulfite, Identification (IR), Impurities, pH, Specific/Optical Rotation, and Water as determined by the stability indicating report. Appearance, Dextrins, Soluble Starch, and Sulfite, and Identification (IR) results up to T_6 met requirements and were not analyzed as they are qualitative. Impurity testing is reported as less than the specification and therefore cannot be analyzed with a shelf life plot.

2. DEFINITIONS:

2.1 LS: Lower Specification

2.2 US: Upper Specification

3. SAMPLE DESIGNATION:

Samples initially placed in the Accelerated Stability Testing Program consist of the initial process validation batches TE3200-001-0219-PV, TE3200-002-0219-PV, TE3200-003-0219-PV, and TE3200-004-0219-PV. Stability samples from each of these batches were put into two different packaging types, Polyethylene Liner/Polyethylene Pail (P/P) and Labline (LL). The type of packaging utilized in the Stability Study was based on BioSpectra packaging.

4. STORAGE:

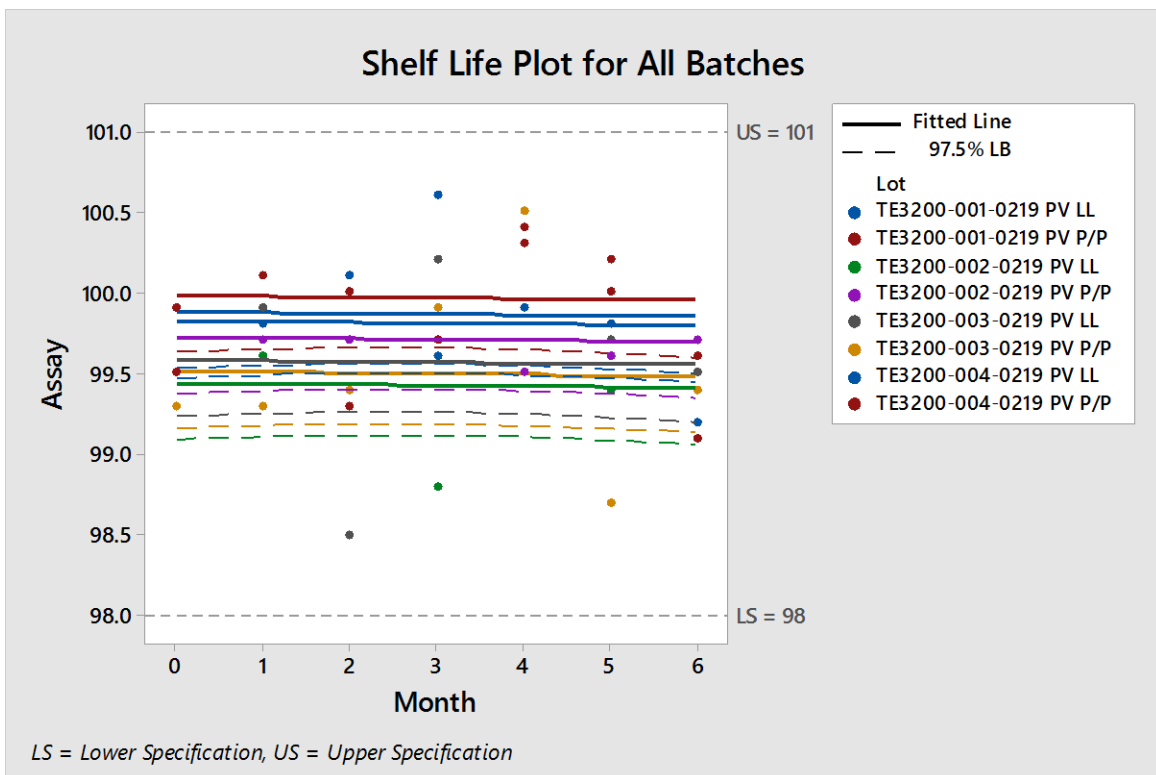
Storage conditions have been continuously measured and recorded utilizing MadgeTech loggers located in the Accelerated Stability Chamber (H02SC01) located in Room H02. The temperature is set to $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and the relative humidity is set to $75\% \pm 5\%$.

5. INVESTIGATIONS:

BDI19-71 and BDI19-122 are the investigations associated with the Stability Testing Program for Trehalose, Dihydrate Accelerated Stability Study. Details regarding these investigations can be found in the Quality Assurance Department and are also attached to this report in the ensur Document Management System as supporting documents.

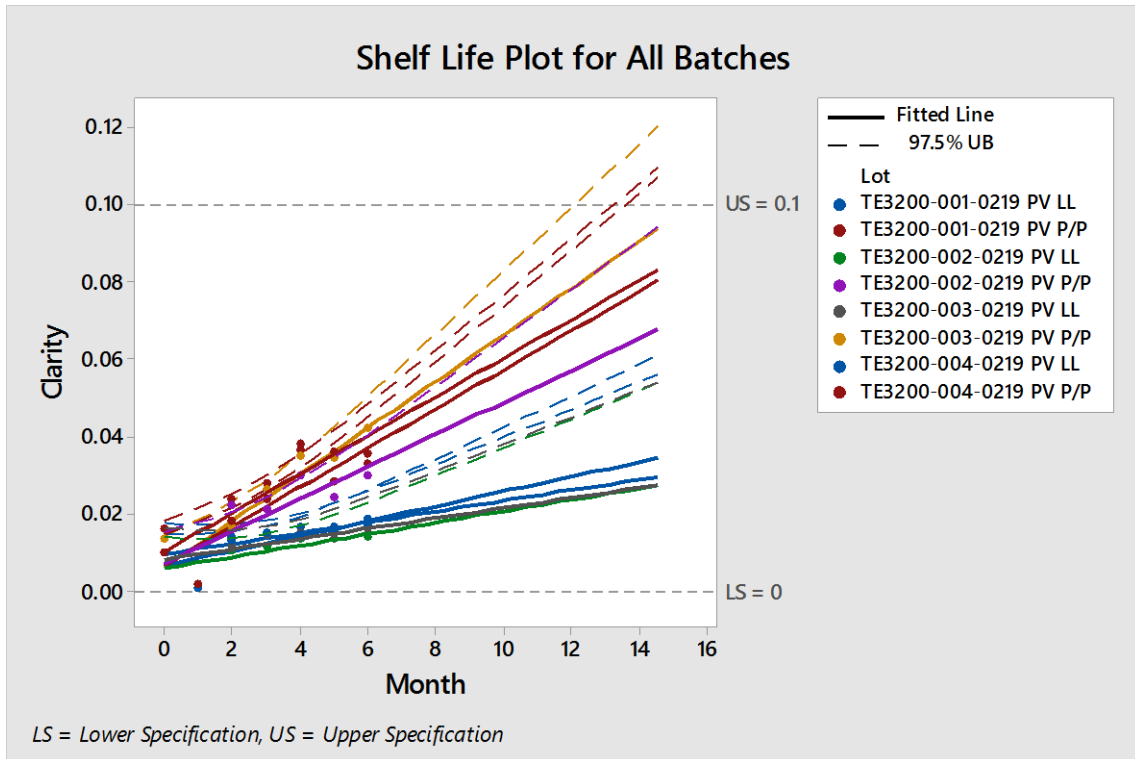
6. GRAPHICAL ANALYSIS:

Graph 1: Assay (%) All Packaging Types



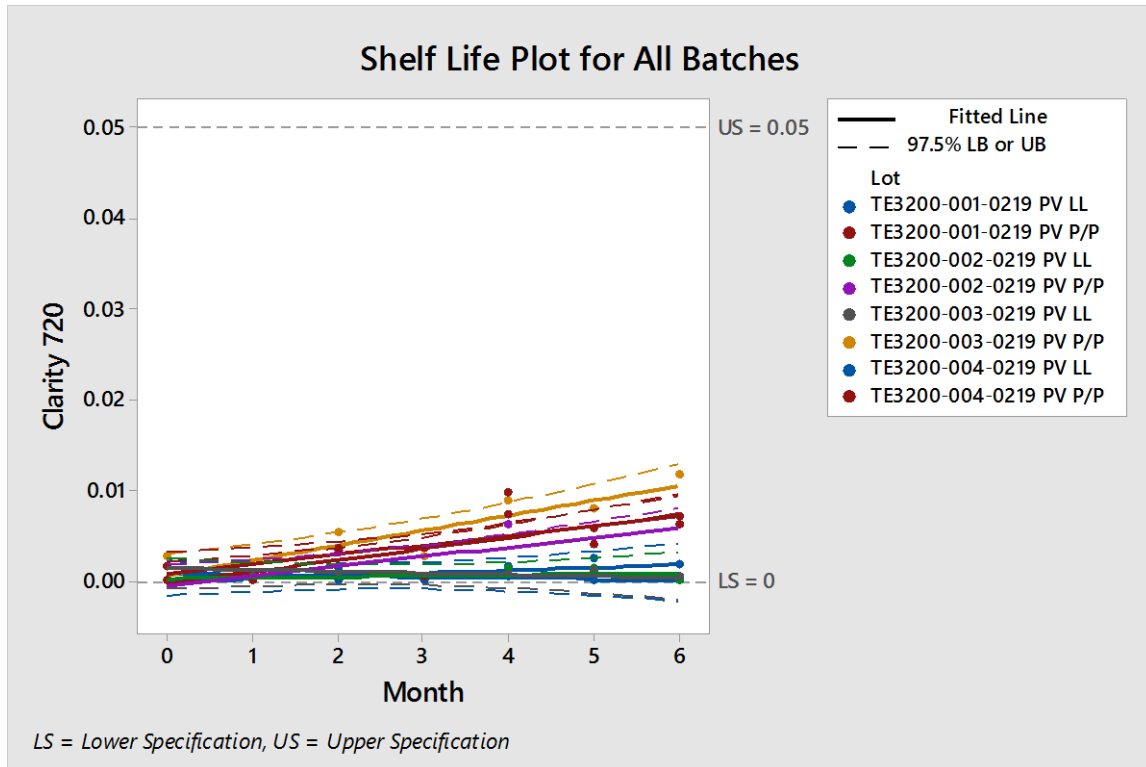
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

Graph 2: Color and Clarity of Solution (A420-A720) All Packaging Types



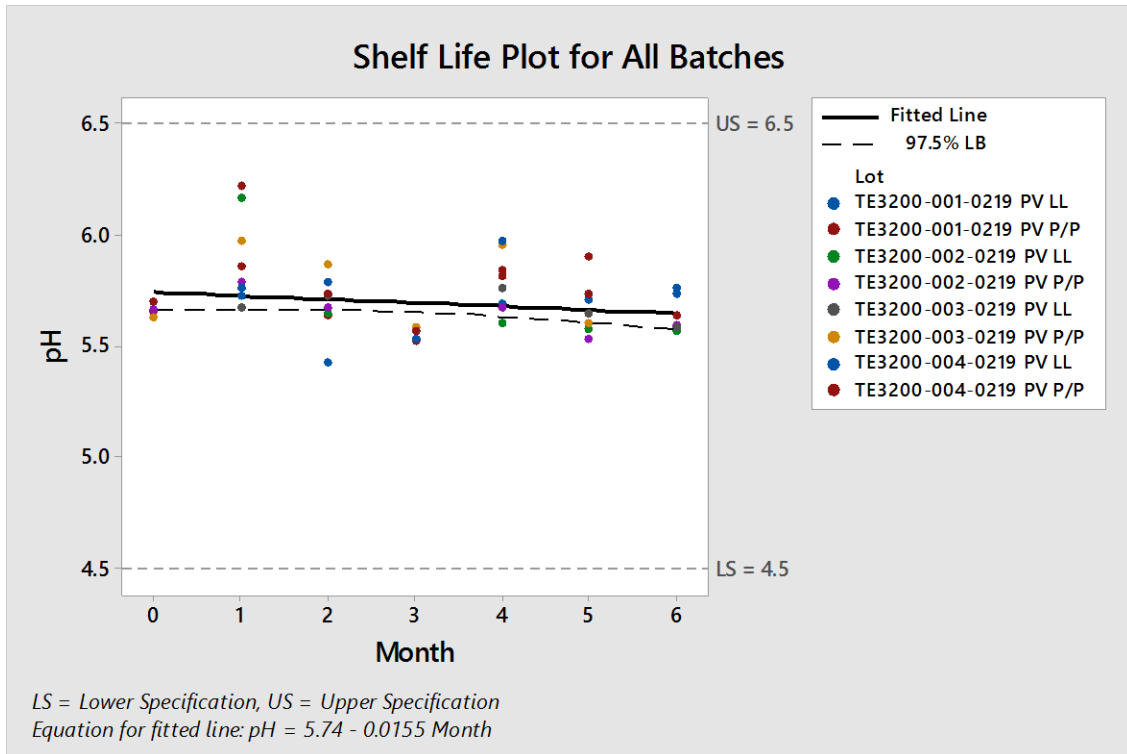
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

Graph 3. Color and Clarity of Solution (A720) All Packaging Types



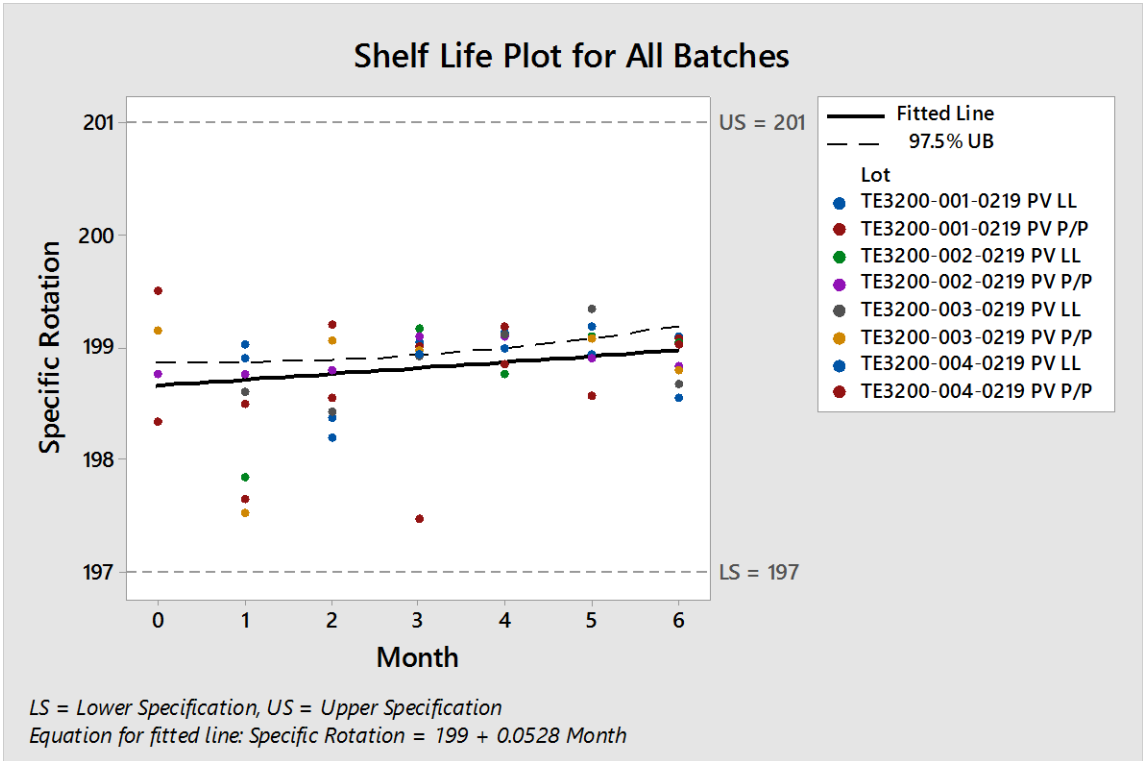
The mean response slope is not significantly different from zero; therefore, no shelf life estimate can be determined.

Graph 4. pH @ 25°C ± 2°C All Packaging Types



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

Graph 5. Specific/Optical Rotation All Packaging Types



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

| Lot Designation | Analysis | Spec. | T ₀ | T ₁ | T ₂ | T ₃ | T ₄ | T ₅ | T ₆ |
|--------------------|--|---------------------------------------|---------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---------------------------------------|
| | Impurity-Maltotriose (Impurity B) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity-Total Impurities with RRT <1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity – Total Impurities with RRT >1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity-Glucose (Impurity A) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity-Any Other Impurities | ≤0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% |
| | Impurity-Sum of Glucose, Maltotriose, and Other Impurities | ≤1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% |
| | pH @ 25°C | 4.5-6.5 | 5.7 @ 23.2°C | 5.8 @ 23.1°C | 5.7 @ 23.1°C | 5.6 @ 23.0°C | 5.7 @ 25.0°C | 5.5 @ 23.1°C | 5.6 @ 23.1°C |
| | Specific Rotation/Optical Rotation | +197 to +201° @ 20°C | +199° | +199° | +199° | +199° | +199° | +199° | +199° |
| | Water (by KF Titration) | 9.0-11.0% | 9.5% | 9.8% | 9.6% | 9.4% | 10.0% | 9.6% | 9.6% |
| TE3200-003-0219-PV | Appearance and Color | White to Off-White Crystalline Powder | White to Off-White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White to Off-White Crystalline Powder |
| | Assay | 98.0-101.0% | 99.3% | 99.3% | 99.4% | 99.9% | 100.5% | 98.7% | 99.4% |
| | Color and Clarity of Solution | A420-A720 ≤0.100 | 0.013 | 0.002 | 0.017 | 0.026 | 0.035 | 0.034 | 0.042 |
| | | A720 ≤0.050 | 0.003 | 0.000 | 0.005 | 0.003 | 0.009 | 0.008 | 0.012 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Impurity-Maltotriose (Impurity B) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity-Total Impurities with RRT <1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity – Total Impurities with RRT >1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity-Glucose (Impurity A) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity-Any Other Impurities | ≤0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% |
| | Impurity-Sum of Glucose, Maltotriose, and Other Impurities | ≤1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% |
| pH @ 25°C | 4.5-6.5 | 5.6 @ 23.3°C | 6.0 @ 23.1°C | 5.9 @ 23.0°C | 5.6 @ 23.0°C | 6.0 @ 26.7°C | 5.6 @ 23.1°C | 5.6 @ 25.0°C | |

| Lot Designation | Analysis | Spec. | T ₀ | T ₁ | T ₂ | T ₃ | T ₄ | T ₅ | T ₆ |
|-------------------------|---|---------------------------------------|---------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---------------------------------------|
| | Specific Rotation/Optical Rotation | +197 to +201° @ 20°C | +199° | +198° | +199° | +199° | +199° | +199° | +199° |
| | Water (by KF Titration) | 9.0-11.0% | 9.6% | 9.7% | 9.7% | 9.6% | 10.1% | 9.7% | 9.4% |
| TE3200-004-0219-PV | Appearance and Color | White to Off-White Crystalline Powder | White to Off-White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White to Off-White Crystalline Powder |
| | Assay | 98.0-101.0% | 99.9% | 100.1% | 100.0% | 99.7% | 100.3% | 100.2% | 99.6% |
| | Color and Clarity of Solution | A420-A720 ≤0.100 | 0.010 | 0.002 | 0.018 | 0.024 | 0.038 | 0.028 | 0.033 |
| | | A720 ≤0.050 | 0.000 | 0.000 | 0.004 | 0.001 | 0.010 | 0.004 | 0.007 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Impurity- Maltotriose (Impurity B) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity- Total Impurities with RRT <1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity – Total Impurities with RRT >1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity- Glucose (Impurity A) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% |
| | Impurity- Any Other Impurities | ≤0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% |
| | Impurity- Sum of Glucose, Maltotriose, and Other Impurities | ≤1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% |
| | pH @ 25°C | 4.5-6.5 | 5.7 @ 23.6°C | 6.2 @ 23.0°C | 5.7 @ 23.0°C | 5.6 @ 23.0°C | 5.8 @ 24.9°C | 5.7 @ 23.1°C | 5.6 @ 23.1°C |
| | Specific Rotation/Optical Rotation | +197 to +201° @ 20°C | +199° | +198° | +199° | +199° | +197° | +199° | +199° |
| Water (by KF Titration) | 9.0-11.0% | 9.5% | 9.8% | 9.7% | ¹ | 9.6% | 9.5% | 9.6% | |

¹ Test interval result not reportable, refer to BDI19-122.

| Lot Designation | Analysis | Spec. | T ₀ | T ₁ | T ₂ | T ₃ | T ₄ | T ₅ | T ₆ | |
|--|--|--|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--|-------|
| | Impurity- Total Impurities with RRT <1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity – Total Impurities with RRT >1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Glucose (Impurity A) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Any Other Impurities | ≤0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | |
| | Impurity- Sum of Glucose, Maltotriose, and Other Impurities | ≤1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | |
| | pH @ 25°C | 4.5-6.5 | 5.7 @ 23.2°C | 6.2 @ 23.5°C | 5.6 @ 23.4°C | 5.6 @ 23.1°C | 5.6 @ 25.7°C | 5.6 @ 23.1°C | 5.6 @ 23.1°C | |
| | Specific Rotation/Optical Rotation | +197 to +201° @ 20°C | +199° | +198° | +199° | +199° | +199° | +199° | +199° | |
| | Water (by KF Titration) | 9.0-11.0% | 9.5% | 10.0% | 9.7% | 9.8% | 9.6% | 9.6% | 9.6% | |
| TE3200-003- 0219-PV | Appearance and Color | White to Off-White Crystalline Powder | White to Off-White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White to Off-White Crystalline Powder | |
| | Assay | 98.0- 101.0% | 99.3% | 99.9% | 98.5% | 100.2% | 99.9% | 99.7% | 99.5% | |
| | Color and Clarity of Solution | A420-A720 ≤0.100 | 0.013 | 0.001 | 0.012 | 0.015 | 0.015 | 0.015 | 0.014 | 0.016 |
| | | A720 ≤0.050 | 0.003 | 0.001 | 0.001 | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | |
| | Impurity- Maltotriose (Impurity B) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Total Impurities with RRT <1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity – Total Impurities with RRT >1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Glucose (Impurity A) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Any Other Impurities | ≤0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | |
| | Impurity- Sum of Glucose, Maltotriose, and Other Impurities | ≤1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | |
| | pH @ 25°C | 4.5-6.5 | 5.6 @ 23.3°C | 5.7 @ 23.4°C | 5.7 @ 23.4°C | 5.6 @ 23.0°C | 5.8 @ 25.7°C | 5.6 @ 23.2°C | 5.6 @ 23.1°C | |
| Specific Rotation/Optical Rotation | +197 to +201° @ 20°C | +199° | +199° | +198° | +199° | +199° | +199° | +199° | | |

| Lot Designation | Analysis | Spec. | T ₀ | T ₁ | T ₂ | T ₃ | T ₄ | T ₅ | T ₆ | |
|-------------------------|---|---------------------------------------|---------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---------------------------------------|-------|
| | Water (by KF Titration) | 9.0-11.0% | 9.6% | 10.1% | 9.8% | 9.6% | 9.6% | 9.5% | 9.7% | |
| TE3200-004-0219-PV | Appearance and Color | White to Off-White Crystalline Powder | White to Off-White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White Crystalline Powder | White to Off-White Crystalline Powder | |
| | Assay | 98.0-101.0% | 99.9% | 99.8% | 100.1% | 99.6% | 99.9% | 100.2% | 99.2% | |
| | Color and Clarity of Solution | A420-A720 ≤0.100 | 0.010 | 0.001 | 0.013 | 0.015 | 0.015 | 0.015 | 0.017 | 0.017 |
| | | A720 ≤0.050 | 0.000 | 0.000 | 0.002 | 0.000 | 0.000 | 0.000 | 0.002 | 0.002 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | |
| | Impurity- Maltotriose (Impurity B) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Total Impurities with RRT <1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity – Total Impurities with RRT >1.0 | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Glucose (Impurity A) | ≤0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | <0.5% | |
| | Impurity- Any Other Impurities | ≤0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | <0.2% | |
| | Impurity- Sum of Glucose, Maltotriose, and Other Impurities | ≤1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | <1.0% | |
| | pH @ 25°C | 4.5-6.5 | 5.7 @ 23.6°C | 5.8 @ 23.3°C | 5.8 @ 23.4°C | 5.5 @ 23.0°C | 6.0 @ 26.6°C | 5.7 @ 23.1°C | 5.7 @ 27.0°C | |
| | Specific Rotation/Optical Rotation | +197 to +201° @ 20°C | +199° | +199° | +198° | +199° | +199° | +199° | +199° | |
| Water (by KF Titration) | 9.0-11.0% | 9.5% | 9.9% | 9.6% | 9.7% | 9.7% | 9.5% | 9.0% | | |

8. CONCLUSION:

All data met the specifications set forth in the Stability Program. Trehalose, Dihydrate is currently undergoing a stability shelf life Long-Term study in accordance with BioSpectra's Stability Program. The proposed retest period is 24 months based on information obtained from development, industry review, and raw material supply chain. This retest period may be used for material represented by the Certificate of Analysis unless otherwise notified by BioSpectra. Additional time may be given based on historical and current data with appropriate justification if statistical analysis from the Long-Term Stability Study warrants the increase in re-test dating.

9. STATEMENT OF COMMITMENT:

- BioSpectra is responsible for the following regarding Stability Data in this report:
 - 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. 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.
 - If a stability analysis is found to be out of specification, the batch will be withdrawn from the market through communication with the Applicant and any additional customer. Additionally, an investigation will be conducted to determine the possible withdrawal of the batches produced before and after the batch in question.
 - In the event that any out of specification results are confirmed, all authorized users of the material will be notified.



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

TREHALOSE, DIHYDRATE LONG TERM STABILITY REPORT: 2019 VALIDATION LOTS

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1. OVERVIEW:

The purpose of this report is to analyze the data obtained from the Real-Time Stability of Trehalose, Dihydrate manufactured at BioSpectra's Bangor, PA facility. Samples were placed on the Stability Testing Program in May of 2019 to fulfil the requirements of placing all Process Validation Batches manufactured on the Stability Testing Program. The long-term Real-Time Stability Program consists of testing every three months for the first year, every six months for the second year and annually for each subsequent year, notated as T_n, where n represents the number of months on stability. Analysis has been conducted thus far for a total of twenty-four months. At the end of the study, a total of thirty-six months of data will be analyzed to assure that the manufactured material remains stable under the specified conditions and for the specified interval of time. The analysis of the compiled data may be used to re-evaluate the retest period for future lots of manufactured material.

This Real-Time Stability report assesses the stability of four lots of Trehalose, Dihydrate that have been part of the Real-Time Stability program for twenty-four months. The four lots will continue on the Stability program until timepoint thirty-six is reached. The study includes the following analyses: Appearance; Assay; Color and Clarity of Solution (A720 and A420-A720); Dextrins, Soluble Starch, and Sulfite; Identification Test A (UATR); Maltotriose (Impurity B); Total Impurities with RRT < 1.0; Total Impurities with RRT > 1.0; Glucose (Impurity A); Any Other Impurities; Sum of Glucose, Maltotriose, and Other Impurities; pH @ 25°C; Specific Rotation/Optical Rotation; and Water by Karl Fischer titration. Results from all analyses are summarized in Table 2.

The stability program is designed to analyze for the stability indicating analyses established for a product in accordance with the Stability Testing Program DCN: BSI-SOP-0136. The specifications for the stability indicating analyses are established in accordance with the Stability Indication Protocol DCN: 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 Trehalose, Dihydrate. The following Product Codes are commercially available.

- TRED-3250
- TRED-3251
- TRED-3252
- TRED-3253

2. REFERENCES:

- 2.1. BSI-SOP-0136, Stability Testing Program
- 2.2. BSI-SOP-0146, Stability Inventory
- 2.3. Current USP
- 2.4. ICH Q1

3. SAMPLE DESIGNATION:

Samples placed on the Stability Testing Program consisted of four Trehalose, Dihydrate Process Validation batches. Stability samples from each of the batches were separated into different packaging configurations, as dictated by the packaging configurations offered to BioSpectra customers. Refer to Table 1 below for packaging configurations and corresponding lots.

TABLE 1: PACKAGING CONFIGURATION

| Packaging Configurations | Description |
|--------------------------------|--|
| Poly/Poly (P/P) | Samples are individually placed into small poly bags and are sealed with a zip tie. All samples are then placed into a poly pail and sealed. |
| Lab Screw-Top Bottle (Labline) | Samples are individually placed into Lab Screw-Top Bottles and are sealed with tamper evident lids. |

4. STORAGE:

At the start of this stability study, Trehalose, Dihydrate stability samples were being stored in the Zone M Warehouse. The storage conditions in the Zone M Warehouse are 10-40°C.

From May 19, 2019 through September 25, 2019, the samples were stored in the Zone M Warehouse. The temperature was monitored continuously using MadgeTech data loggers, with an allowable temperature range of 10 – 40°C. The maximum temperature of the warehouse during this timeframe was 33.67°C, the minimum temperature was 18.19°C, the average temperature was 26.22°C, and the average mean kinetic temperature was 26.31°.

On September 25, 2019, all stability samples were moved from the Zone M Warehouse to the Long-term stability (LTS) chamber, where they remained until the final set of samples was pulled for the T=36 time interval in May 2022. The temperature was monitored continuously using MadgeTech data loggers, with an allowable temperature range of 23°C to 27°C, and relative humidity range of 55% to 65%. The maximum temperature of the LTS chamber during this time was 27.80°C, the minimum temperature was 21.75°C, the average temperature was 25.45°C, and the average mean kinetic temperature was 25.46°C. The maximum relative humidity of the LTS chamber during this time was 72.4%, the minimum relative humidity was 30.3%, and the average relative humidity was 61.3%. Any temperature and relative humidity excursions not explained by documented entry into and out of the LTS chamber will be documented in an investigation in section 5.

5. INVESTIGATIONS:

- 5.1. BDI19-71: Trehalose T_0 Stability samples were not tested within five business days of the sampling due date, as stated in the Stability Testing Program. The stability indicating protocol was still in the approval process. The final report was completed on May 17, 2019 to allow for Trehalose to be put on stability. Samples were put on stability on 5/19/19.
- 5.2. BDI19-96: Planned deviation for testing of Trehalose T_3 Stability samples due to instrument demand, Assay and Impurities were not able to be performed within the allowed 5-day window given by the Stability Testing Program.
- 5.3. BLI20-15: TE3200-003-0219-PV Labline T_{12} received OOS results for Any Other Impurities. All re-tests met requirements, and the official result is reported as < 0.2%. The root cause was determined to be analyst error.
- 5.4. BLI20-36: TE3200-001-0219-PV Labline T_{18} and TE3200-002-0219-PV T_{18} Labline obtained OOS Assay results. During review of data, it was found that the integration was inconsistent during sample and standard runs which in turn raised the assay values outside the accepted range. All re-tests met the required specification.
- 5.5. BDI22-61: This investigation was due to missing temperature and humidity data for the Long Term Stability Chamber for the time period of 01/28/22 to 02/09/22. The MadgeTech data logger was restarted and functioned properly afterwards. The Analog Chart recordings were used to confirm there were no deviations for this time period, and the incident had no impact on the samples.
- 5.6. BDI22-138: There was a brief period of time on 04/26/22 that humidity readings for the Long Term Stability Chamber were less than the minimum specification. Root cause was determined to be a faulty valve that regulates the flow of humid air produced by the chamber's humidifier. The preventative maintenance team was alerted to the alarm in the room signaling the issue, and corrected the issue. Due to the short time frame of the low humidity readings, there was no lasting impact on the samples.
- 5.7. BDI22-143: The investigation was due to missing temperature and humidity data points for the Long Term Stability Chamber due to an issue with the MadgeTech Data Logger. The Analog Chart recordings were used to confirm there were no deviations for this time period, and the incident had no impact on the samples.

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6. LOT EVALUATION:

TABLE 2: REAL-TIME DATA

| Lot Number | Analysis | Specification | T ₀ | T ₃ | T ₆ | T ₉ | T ₁₂ | T ₁₈ | T ₂₄ | T ₃₆ |
|----------------------------|---|---------------------------------------|---------------------------------------|--------------------------|---------------------------------------|---------------------------------------|--------------------------|---------------------------------------|--------------------------|---------------------------------------|
| TE3200-001-0219-PV Labline | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder |
| | Assay | 98.0% - 101.0% | 99.5% | 99.5% | 100.7% | 100.3% | 100.2% | 100.5% | 99.7% | 100.1% |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | 0.0017 | < 0.003 | < 0.003 | < 0.003 | < 0.003 | < 0.003 | < 0.003 | < 0.003 |
| | Color and Clarity of Solution (A420-A720) | ≤ 0.100 a.u. | 0.0162 | 0.0147 | 0.0140 | 0.0127 | 0.0121 | 0.0107 | 0.0115 | 0.0166 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT < 1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT > 1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| | pH @ 25°C | 4.5 – 6.5 | 5.65 @ 23.3°C | 5.88 @ 23.2°C | 5.61 @ 26.2°C | 5.52 @ 23.6°C | 5.59 @ 23.3°C | 5.49 @ 23.1°C | 5.62 @ 25.3°C | 5.70 @ 24.1°C |
| | Specific Rotation/ Optical Rotation | +197°C - +201°C @ 20°C | +198.33° | +199.29° | +198.98° | +198.82° | +199.17° | +199.02° | +199.20° | +199.31° |
| Water (by KF Titration) | 9.0 – 11.0% | 9.31% | 9.32% | 9.75% | 9.57% | 8.97% | 9.57% | 9.53% | 9.53% | |
| TE3200-001-0219-PV P/P | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder |
| | Assay | 98.0% - 101.0% | 99.5% | 99.1% | 99.6% | 100.1% | 100.4% | 100.9% | 99.9% | 100.3% |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | 0.0017 | < 0.003 | 0.0026 | 0.0046 | 0.0032 | 0.0032 | 0.0063 | 0.0024 |
| | Color and Clarity of Solution (A420-A720) | ≤ 0.100 a.u. | 0.0162 | 0.0151 | 0.0227 | 0.0246 | 0.0253 | 0.0280 | 0.0389 | 0.0341 |

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| Lot Number | Analysis | Specification | T ₀ | T ₃ | T ₆ | T ₉ | T ₁₂ | T ₁₈ | T ₂₄ | T ₃₆ |
|--|---|---------------------------------------|---------------------------------------|--------------------------|---------------------------------------|---------------------------------------|--------------------------|---------------------------------------|--------------------------|---------------------------------------|
| TE3200-001-0219-PV P/P | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| | pH @ 25°C | 4.5 – 6.5 | 5.65 @ 23.3°C | 5.52 @ 23.1°C | 5.57 @ 24.4°C | 5.59 @ 23.1°C | 5.61 @ 23.3°C | 5.58 @ 23.2°C | 5.69 @ 25.0°C | 5.66 @ 23.0°C |
| | Specific Rotation/Optical Rotation | +197°C - +201°C @ 20°C | +198.33° | +199.01° | +198.92° | +199.23° | +198.77° | +199.12° | +199.35° | +199.12° |
| | Water (by KF Titration) | 9.0 – 11.0% | 9.31% | 10.23% | 9.64% | 9.45% | 9.75% | 9.56% | 9.64% | 9.61% |
| TE3200-002- TE3200-002-0219-PV Labline | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder |
| | Assay | 98.0% - 101.0% | 99.9% | 99.0% | 99.4% | 99.8% | 100.5% | 100.5% | 100.2% | 100.3% |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | < 0.003 | < 0.003 | 0.0024 | < 0.003 | < 0.003 | < 0.003 | < 0.003 | < 0.003 |
| | Color and Clarity of Solution (A420-A720) | ≤ 0.100 a.u. | 0.0098 | 0.0118 | 0.0124 | 0.0097 | 0.0132 | 0.0091 | 0.0102 | 0.0158 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |

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| Lot Number | Analysis | Specification | T ₀ | T ₃ | T ₆ | T ₉ | T ₁₂ | T ₁₈ | T ₂₄ | T ₃₆ |
|------------------------------------|---|--|--|--------------------------------|--|--|--------------------------------|--|--------------------------------|--|
| | pH @ 25°C | 4.5 – 6.5 | 5.66 @ 23.2°C | 5.54 @ 23.2°C | 5.81 @ 24.4°C | 5.53 @ 23.2°C | 5.52 @ 23.2°C | 5.66 @ 23.1°C | 5.62 @ 25.2°C | 5.66 @ 23.3°C |
| | Specific Rotation/ Optical Rotation | +197°C - +201°C @ 20°C | +198.75° | +198.83° | +198.84° | +198.44° | +198.79° | +198.61° | +198.68° | +199.21° |
| | Water (by KF Titration) | 9.0 – 11.0% | 9.47% | 9.55% | 9.93% | 9.62% | 9.25% | 9.57% | 9.63% | 9.58% |
| TE3200-002- TE3200-002-0219-PV P/P | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder |
| | Assay | 98.0% - 101.0% | 99.9% | 99.6% | 99.9% | 99.7% | 100.4% | 99.8% | 99.5% | 100.3% |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | < 0.003 | < 0.003 | 0.0005 | 0.0008 | 0.0002 | 0.0006 | 0.0011 | < 0.003 |
| | Color and Clarity of Solution (A420- A720) | ≤ 0.100 a.u. | 0.0098 | 0.0098 | 0.0133 | 0.0135 | 0.0151 | 0.0178 | 0.0240 | 0.0260 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| | pH @ 25°C | 4.5 – 6.5 | 5.66 @ 23.2°C | 5.56 @ 23.2°C | 5.89 @ 26.9°C | 5.57 @ 23.4°C | 5.53 @ 23.5°C | 5.59 @ 23.2°C | 5.63 @ 24.8°C | 5.77 @ 23.8°C |
| | Specific Rotation/ Optical Rotation | +197°C - +201°C @ 20°C | +198.75° | +199.20° | +198.99° | +198.83° | +199.22° | +199.41° | +199.32° | +198.89° |
| Water (by KF Titration) | 9.0 – 11.0% | 9.47% | 9.56% | 9.13% | 9.47% | 9.04% | 9.52% | 9.69% | 9.59% | |
| TE3200-003-0219-PV Labline | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder |
| | Assay | 98.0% - 101.0% | 99.3% | 100.2% | 99.3% | 99.5% | 100.6% | 99.6% | 99.7% | 100.8% |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | 0.0027 | < 0.003 | 0.0014 | 0.0009 | 0.0008 | 0.0024 | < 0.003 | < 0.003 |
| | Color and Clarity of Solution (A420- A720) | ≤ 0.100 a.u. | 0.0134 | 0.0120 | 0.0143 | 0.0116 | 0.0131 | 0.0165 | 0.0121 | 0.0175 |

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| Lot Number | Analysis | Specification | T ₀ | T ₃ | T ₆ | T ₉ | T ₁₂ | T ₁₈ | T ₂₄ | T ₃₆ |
|---|---|---------------------------------------|---------------------------------------|--------------------------|---------------------------------------|---------------------------------------|--------------------------|---------------------------------------|--------------------------|---------------------------------------|
| TE3200-003-0219-PV Labline | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| | pH @ 25°C | 4.5 – 6.5 | 5.62 @ 23.3°C | 5.55 @ 23.0°C | 5.76 @ 23.1°C | 5.52 @ 24.0°C | 5.50 @ 23.3°C | 5.62 @ 23.1°C | 5.64 @ 24.6°C | 5.65 @ 23.5°C |
| | Specific Rotation/Optical Rotation | +197°C - +201°C @ 20°C | +199.14° | +198.87° | +198.83° | +198.72° | +198.38° | +198.75° | +199.02° | +198.46° |
| Water (by KF Titration) | 9.0 – 11.0% | 9.63% | 9.87% | 9.94% | 9.63% | 9.29% | 9.59% | 9.57% | 9.59% | |
| TE3200-003-0219-PV P/P | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder |
| | Assay | 98.0% - 101.0% | 99.3% | 99.8% | 99.3% | 99.9% | 100.1% | 99.9% | 99.9% | 100.6% |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | 0.0027 | < 0.003 | 0.0021 | 0.0034 | 0.0037 | 0.0041 | 0.0072 | 0.0046 |
| | Color and Clarity of Solution (A420-A720) | ≤ 0.100 a.u. | 0.0134 | 0.0125 | 0.0215 | 0.0185 | 0.0197 | 0.0228 | 0.0363 | 0.0379 |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | |

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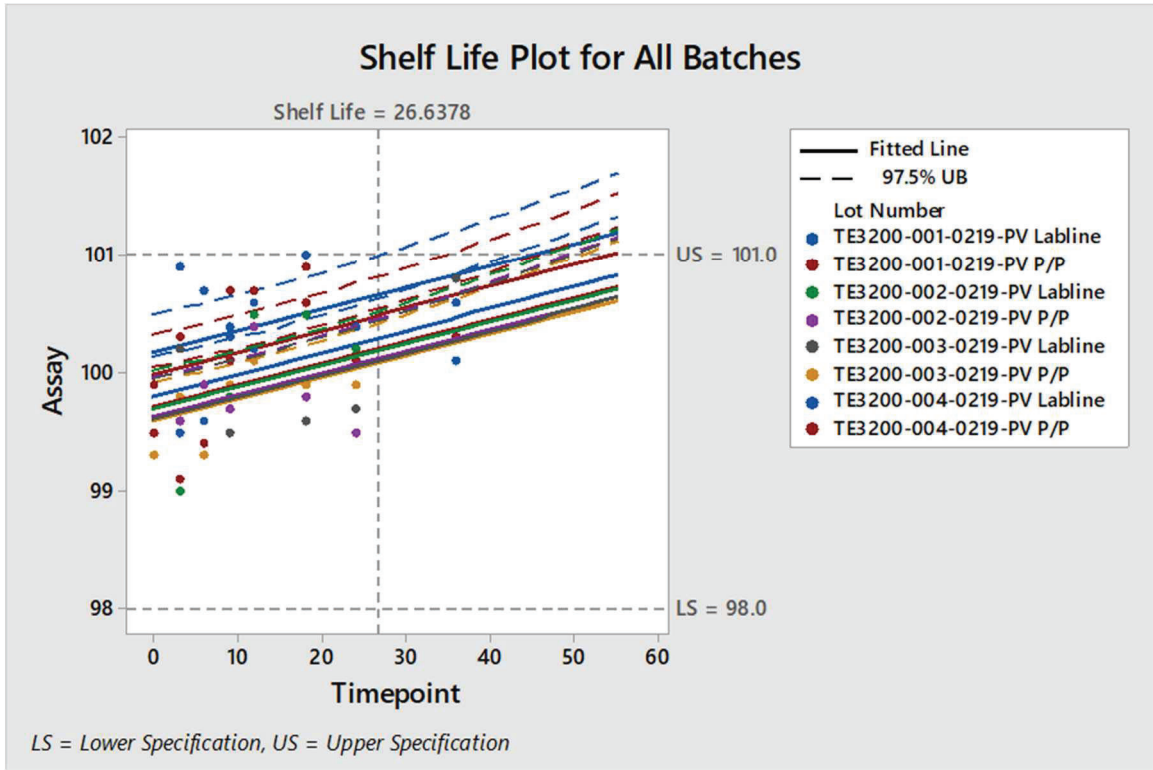
| Lot Number | Analysis | Specification | T ₀ | T ₃ | T ₆ | T ₉ | T ₁₂ | T ₁₈ | T ₂₄ | T ₃₆ | |
|----------------------------|---|--|--|--------------------------------|--|--|--------------------------------|--|--------------------------------|--|-------------------------|
| | pH @ 25°C | 4.5 – 6.5 | 5.62 @ 23.3°C | 5.58 @ 23.1°C | 5.68 @ 26.0°C | 5.59 @ 23.8°C | 5.56 @ 23.5°C | 5.53 @ 23.1°C | 5.61 @ 24.2°C | 5.72 @ 23.7°C | |
| | Specific Rotation/ Optical Rotation | +197°C – +201°C @ 20°C | +199.14° | +199.32° | +198.69° | +198.96° | +199.04° | +198.61° | +199.21° | +199.09° | |
| | Water (by KF Titration) | 9.0 – 11.0% | 9.63% | 9.54% | 9.66% | 9.67% | 8.97% | 9.49% | 9.58% | 9.65% | |
| TE3200-004-0219-PV Labline | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | |
| | Assay | 98.0% - 101.0% | 99.9% | 100.9% | 99.6% | 100.4% | 100.6% | 101.0% | 100.4% | 100.6% | |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | 0.0004 | < 0.003 | 0.0026 | 0.0005 | 0.0002 | < 0.003 | < 0.003 | < 0.003 | |
| | Color and Clarity of Solution (A420- A720) | ≤ 0.100 a.u. | 0.0090 | 0.0127 | 0.0148 | 0.0123 | 0.0117 | 0.0106 | 0.0093 | 0.0153 | |
| | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| | pH @ 25°C | 4.5 – 6.5 | 5.69 @ 23.6°C | 5.56 @ 23.1°C | 5.57 @ 23.8°C | 5.45 @ 23.1°C | 5.52 @ 23.2°C | 5.53 @ 23.2°C | 5.61 @ 24.3°C | 5.57 @ 23.4°C | |
| | Specific Rotation/ Optical Rotation | +197°C - +201°C @ 20°C | +199.49° | +198.89° | +199.17° | +198.54° | +198.98° | +198.79° | +198.66° | +199.20° | |
| | Water (by KF Titration) | 9.0 – 11.0% | 9.53% | 9.33% | 9.68% | 9.35% | 9.08% | 9.54% | 9.65% | 9.69% | |
| TE3200-004-0219-PV P/P | Appearance | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | White Crystalline Powder | White to Off White Crystalline Powder | |
| | Assay | 98.0% - 101.0% | 99.9% | 100.3% | 99.4% | 100.7% | 100.7% | 100.6% | 100.1% | 100.3% | |
| | Color and Clarity of Solution (A720) | ≤ 0.050 a.u. | 0.0004 | < 0.003 | 0.0016 | 0.0007 | 0.0019 | 0.0021 | 0.0018 | 0.0007 | |
| | Color and Clarity of Solution (A420- A720) | ≤ 0.100 a.u. | 0.0090 | 0.0090 | 0.0149 | 0.0143 | 0.0157 | 0.0208 | 0.0304 | 0.0297 | |

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| Lot Number | Analysis | Specification | T ₀ | T ₃ | T ₆ | T ₉ | T ₁₂ | T ₁₈ | T ₂₄ | T ₃₆ |
|------------------------|---|------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| TE3200-004-0219-PV P/P | Dextrins, Soluble Starch, and Sulfite | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test | Passes Test |
| | Identification Test A (UATR) | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard | Conforms to Standard |
| | Maltotriose (Impurity B) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT <1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Total Impurities with RRT >1.0 | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Glucose (Impurity A) | ≤ 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% | < 0.5% |
| | Any Other Impurities | ≤ 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% | < 0.2% |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| | pH @ 25°C | 4.5 – 6.5 | 5.69 @ 23.6°C | 5.72 @ 23.1°C | 5.50 @ 23.1°C | 5.46 @ 23.3°C | 5.52 @ 23.4°C | 5.58 @ 23.1°C | 5.65 @ 25.2°C | 5.79 @ 23.7°C |
| | Specific Rotation/ Optical Rotation | +197°C - +201°C @ 20°C | +199.49° | +198.88° | +199.17° | +199.30° | +198.75° | +198.79° | +198.73° | +199.17° |
| | Water (by KF Titration) | 9.0 – 11.0% | 9.53% | 9.65% | 9.64% | 9.57% | 8.99% | 9.55% | 9.47% | 9.61% |

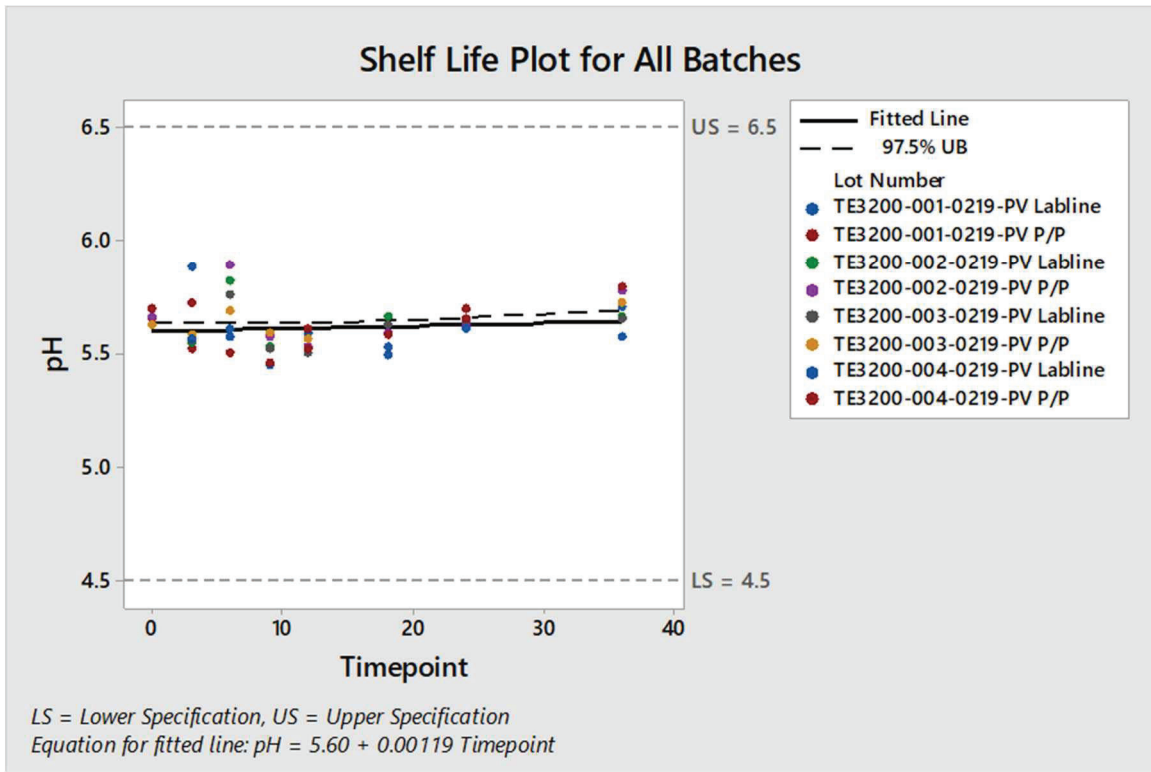
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GRAPH 1: ASSAY



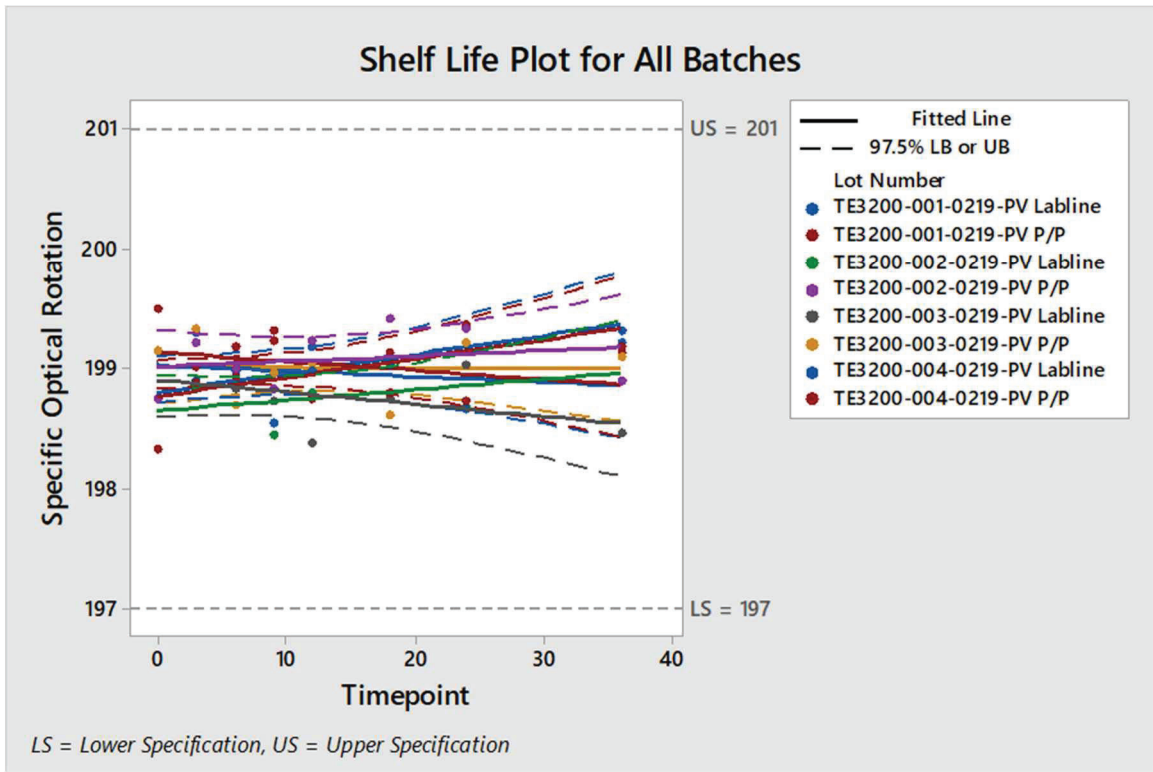
The predicted Shelf-Life for Assay was determined to be 26.6378 months as of the T=36 month time interval, which is the end of this study. All time points did pass the specification for assay throughout the entire study.

GRAPH 2: pH



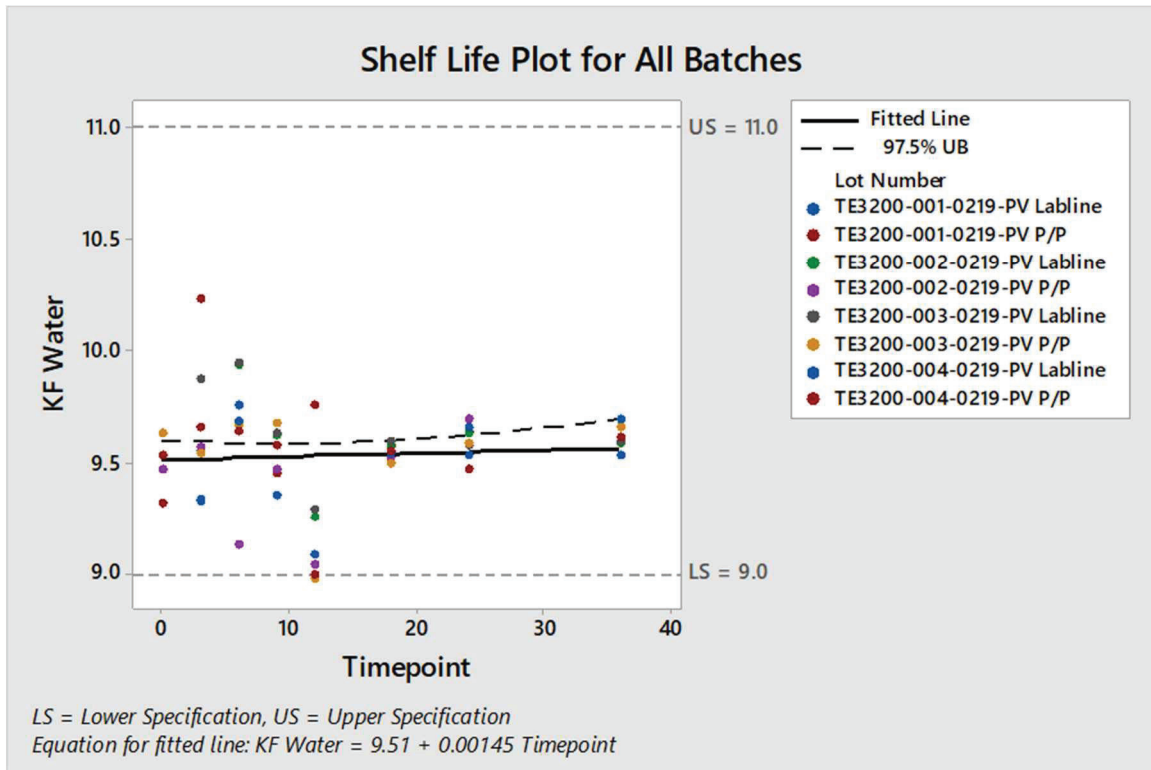
No Shelf-Life was able to be determined for pH, as the mean response slope is not significantly different from zero using 95% confidence. There is no impact to the product or currently assigned retest period of this material.

GRAPH 3: SPECIFIC OPTICAL ROTATION



No Shelf-Life was able to be determined for Specific Optical Rotation, 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 4: KF WATER



No Shelf-Life was able to be determined for Water by Karl Fischer (KF Water), 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 2.4.2.1, 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 standard conditions. Real-Time Stability Data displayed in this report along with the predicted shelf-life plots would support a retest date of 27-months (rounded from 26.6378 months), with Assay being the limiting factor in the predicted model. All the time points did pass specification for all testing, including Assay, up to the 36-month interval which was the end of this study. This stability report supports a retest date of 24 months for Trehalose, Dihydrate manufactured at BioSpectra in the Bangor, PA facility, and upon request a 36-month expiration date may be assigned based on the actual Real Time data obtained.

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8. STATEMENT OF COMMITMENT:

- 8.1. BioSpectra is responsible for the following regarding Stability Data in this report:
 - 8.1.1. All ongoing stability data points obtained from this program will be submitted to the DMF 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.
 - 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 Applicant and any additional customers. 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 result are confirmation, all authorized users of the material will be notified.