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D-GALACTOSE, PLANT DERIVED 2021VALIDATION LOTS REAL TIME STABILITY REPORT

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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 D-Galactose, Plant Derived. 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 Real Time Stability analysis will assess the stability of Galactose validation lots GALP-0121-00004-PV, GALP-0121-00005-PV, GALP-0121-00006-PV, and GALP-0121-00007-PV that completed six (6) months of real-time stability in April 2022 and is scheduled to finish at sixty (60) months in October 2026. This study includes the following analyses: Appearance and Color, Acidity/Alkalinity, Assay, Appearance of Solution, Identification A (USP; UATR), Identification B (USP; HPLC), Specific/Optical Rotation, Water (By Karl Fischer Titration), and Related Substances. 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 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 Galactose. The following Product Codes are commercially available.

- GALP-3250
- GALP-3251

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 four lots of Galactose. Stability samples from these lots were put into P/P and Labline packaging configuration. The samples were packaged in accordance with the Stability Inventory SOP. Reference Table 1, below, for packaging configurations and descriptions. 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
Poly/Poly (P/P)	Samples are individually placed into small polyethylene bags and are sealed with a zip tie. All individual bags are then placed into a poly pail and sealed.
Labline (HDPE Bottle)	Samples are packaged into a HDPE Lab Screw-Top Bottle.

4. STORAGE:

4.1. The Packaging and Storage requirements for Galactose are to be in tightly closed container in a dry and well-ventilated place. For this study, samples were stored in the Real Time Stability Chamber at the Bangor, PA facility. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature (25°C ±2) and relative humidity (60% ±5). For the time period of October 2021 to April 2022 the samples were located in the Real Time Stability Chamber, and all future time point samples remain at this condition. The maximum temperature recorded was 25.98°C, the minimum temperature was 22.63°C, the average temperature was 25.47°C, and the Average Mean Kinetic Temperature was 25.47°C. The maximum relative humidity recorded was 72.34%, the minimum relative humidity was 31.1%, and the average relative humidity was 60.2%. 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. BLI22-01: This laboratory investigation documents an OOS Assay result for sample GALP-0121-00004-PV T=3 Labline. The original result for this sample was OOS low with a result of 96.65%, where the specification for this product is 98.0% to 102.0%. The result of the investigation determined that a preparation error was the root cause. An average of six retests were used to determine the final result for this sample time interval to be 98.96%, which passes specification.

5.2. BLI22-02: This laboratory investigation documents an OOS Appearance of Solution result for GALP-0121-00007-PV T=3 P/P. The original result for this sample was OOS with a result that exceeded the specification of ≤ 3 NTU and could not be considered a clear solution which would result in a passing test. The result of the investigation determined that a contamination issue during sample preparation was the root cause. An average of six retests were used to determine the final result for this sample time interval to be within specification, and be considered a passing test.

5.3. BLI22-06: This laboratory investigation documents an OOS Assay result for samples GALP-0121-00007-PV T=3 P/P and Labline. The original results for these samples were OOS low with a result of 97.91% for P/P and 97.41% for Labline, where the specification for this product is 98.0% to 102.0%. For the P/P sample, the result of six retests had 2 out of the 6 of the results still OOS low, which confirms the original OOS result of 97.91%. This will be the reported value for the sample. For the Labline sample, the results of six retests were within specification and the average of 98.77% was used as the reported value for the sample. The testing for this investigation was not completed by the assigned due date, which resulted in discrepancy investigation BDI22-78.

5.4. BDI22-78: This discrepancy investigation documents BLI22-06 not being completed by the assigned due date.

5.5. BDI22-143: This discrepancy investigation documents the observed deviation in the Real Time Stability Chamber in November 2021.

6. LOT EVALUATION:

TABLE 2A: 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}	T_{48}	T_{60}
GALP-0121-00004-PV P/P	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 06/23/22	Scheduled for 09/23/22	Scheduled for 03/23/23	Scheduled for 09/23/23	Scheduled for 09/23/24	Scheduled for 09/23/25	Scheduled for 09/23/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	100.01	98.12	98.66							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.43	80.49	80.55							
	KF Water	≤ 1.0%	0.15	0.14	0.25							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.08							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	<0.6	<0.6							
	Unspecified (Single)	≤ 1.0%	<1.0	<1.0	<1.0							
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.09	0.08							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2B: 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}	T_{48}	T_{60}
GALP-0121-00004-PV Labline	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 06/23/22	Scheduled for 09/23/22	Scheduled for 03/23/23	Scheduled for 09/23/23	Scheduled for 09/23/24	Scheduled for 09/23/25	Scheduled for 09/23/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	100.01	98.96	99.42							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.43	80.41	80.56							
	KF Water	≤ 1.0%	0.15	0.13	0.19							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.09							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	<0.6	<0.6							
	Unspecified (Single)	≤ 1.0%	<1.0	<1.0	<1.0							
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.13	0.09							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2C: 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}	T_{48}	T_{60}
GALP-0121-00005-PV P/P	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 06/28/22	Scheduled for 09/28/22	Scheduled for 03/28/23	Scheduled for 09/28/23	Scheduled for 09/28/24	Scheduled for 09/28/25	Scheduled for 09/28/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	98.69	98.71	99.85							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.49	80.51	80.47							
	KF Water	≤ 1.0%	0.19	0.22	0.13							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.09							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	0.05	0.05							
	Unspecified (Single)	≤ 1.0%	<1.0	0.06	<1.0							
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.19	0.14							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2D: 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}	T_{48}	T_{60}
GALP-0121-00005-PV Labline	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 06/28/22	Scheduled for 09/28/22	Scheduled for 03/28/23	Scheduled for 09/28/23	Scheduled for 09/28/24	Scheduled for 09/28/25	Scheduled for 09/28/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	98.69	98.88	100.00							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.49	80.38	80.57							
	KF Water	≤ 1.0%	0.19	0.19	0.16							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.10	0.09							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	<0.6	0.05							
	Unspecified (Single)	≤ 1.0%	<1.0	0.16	<1.0							
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.30	0.14							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2E: 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}	T_{48}	T_{60}
GALP-0121-00006-PV P/P	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 06/29/22	Scheduled for 09/29/22	Scheduled for 03/29/23	Scheduled for 09/29/23	Scheduled for 09/29/24	Scheduled for 09/29/25	Scheduled for 09/29/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	98.57	98.49	98.75							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.41	80.49	80.43							
	KF Water	≤ 1.0%	0.23	0.22	0.14							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.11	0.10	0.10							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	0.05	0.05							
	Unspecified (Single)	≤ 1.0%	<1.0	0.06	<1.0							
	[4]Total Organic Impurities	≤ 1.0%	0.16	0.20	0.15							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2F: 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}	T_{48}	T_{60}
GALP-0121-00006-PV Labline	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 06/29/22	Scheduled for 09/29/22	Scheduled for 03/29/23	Scheduled for 09/29/23	Scheduled for 09/29/24	Scheduled for 09/29/25	Scheduled for 09/29/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	98.57	98.87	98.59							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.41	80.45	80.58							
	KF Water	≤ 1.0%	0.23	0.21	0.17							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.11	0.10	0.10							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	0.05	0.05							
	Unspecified (Single)	≤ 1.0%	<1.0	0.05	<1.0							
	[4]Total Organic Impurities	≤ 1.0%	0.16	0.19	0.15							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2G: 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}	T_{48}	T_{60}
GALP-0121-00007-PV P/P	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 07/06/22	Scheduled for 10/06/22	Scheduled for 04/06/23	Scheduled for 10/06/23	Scheduled for 10/06/24	Scheduled for 10/06/25	Scheduled for 10/06/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	99.46	[4]97.91	99.40							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.38	80.47	80.47							
	KF Water	≤ 1.0%	0.11	0.20	0.24							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.08	0.07	0.06							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	<0.6	0.05							
	Unspecified (Single)	≤ 1.0%	<1.0	<1.0	<1.0							
	[5]Total Organic Impurities	≤ 1.0%	0.12	0.07	0.11							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Result is OOS, refer to BLI22-06
[5]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2H: 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}	T_{48}	T_{60}
GALP-0121-00007-PV Labline	[1]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	Scheduled for 07/06/22	Scheduled for 10/06/22	Scheduled for 04/06/23	Scheduled for 10/06/23	Scheduled for 10/06/24	Scheduled for 10/06/25	Scheduled for 10/06/26
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test							
	Assay	98.0 – 102.0%	99.46	98.77	98.91							
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test							
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS							
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS							
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.38	80.48	80.41							
	KF Water	≤ 1.0%	0.11	0.20	0.13							
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.08	0.07	0.06							
	Galacturonic Acid	≤ 0.6%	<0.6	<0.6	<0.6							
	Dextrose	≤ 0.6%	<0.6	<0.6	<0.6							
	Tagatose	≤ 0.6%	<0.6	<0.6	<0.6							
	Dulcitol	≤ 0.6%	<0.6	<0.6	<0.6							
	Arabinose	≤ 0.6%	0.05	0.05	<0.6							
	Unspecified (Single)	≤ 1.0%	<1.0	<1.0	<1.0							
	[3]Total Organic Impurities	≤ 1.0%	0.12	0.12	0.06							

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

7. CONCLUSION:

7.1. In regards to the Real Time Stability Study for Galactose, all data met the specifications set forth in the Stability Testing Program except for the Assay result for lot GALP-0121-00007-PV T=3 P/P. This OOS result led to laboratory investigation BLI22-06 which confirmed the original Assay result of 97.9%, which is out of specification (98.0% to 102.0%). The Labline packaged sample for this time interval did pass specification, and therefore indicates that the failure was an individual sample failure and not a lot failure at T=3. The data collected from the completed Accelerated study and the T=6 testing interval for the same validation lot met specification. Therefore, it was concluded to continue to monitor this batch on the stability program without further action and when a sufficient amount of data points is collected, the data will be statistically evaluated to determine if the T=3 results for Assay is an outlier, and if that data should be included in determining the shelf life plot for this lot and packaging configuration.

Due to the limited number of data points available for the Real Time Stability Study, the retest date will remain at 2 years (24 months) based on BSI-ATM-0023. The Accelerated Stability Study BSI-RPT-0990 for Galactose does have data along with predicted shelf-life plots that shows at least a 9 month retest date at an accelerated temperature and humidity condition for Galactose manufactured at BioSpectra in the Bangor, PA facility.

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 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.

8.2. 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.

8.2.1. 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.

8.3. 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

GALACTOSE 2021VALIDATION LOTS ACCELERATED STABILITY REPORT

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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 Galactose. Testing intervals are designated by T_n, where *n* equals the number of months on stability. Testing is performed every month for six months 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 Accelerated Stability analysis will assess the stability of Galactose validation lots GALP-0121-00004-PV, GALP-0121-00005-PV, GALP-0121-00006-PV, and GALP-0121-00007-PV that completed six (6) months of accelerated stability in April 2022. This study includes the following analyses: Appearance, Acidity – Alkalinity, Assay, Appearance of Solution, ID A(UATR), ID B (HPLC), Specific Optical Rotation, Karl Fischer Water (KF), and Related Substances. 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 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 Galactose. The following Product Codes are commercially available.

- GALP-3250
- GALP-3251

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 four lots of Galactose. Stability samples from these lots were put into P/P and Labline packaging configurations. The samples were packaged in accordance with the Stability Inventory SOP. Reference Table 1, below, for packaging configurations and descriptions. 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
Poly/Poly (P/P)	Samples are individually placed into small polyethylene bags and are sealed with a zip tie. All individual bags are then placed into a poly pail and sealed.
Labline (HDPE Bottle)	Samples are packaged into a HDPE Lab Screw-Top Bottle

4. STORAGE:

4.1. The Packaging and Storage requirements for Galactose are to be in tightly closed container in a dry and well-ventilated place. For this study, samples were stored in the Accelerated Stability Chamber at the Bangor, PA facility. Storage conditions have been continuously measured and recorded utilizing MadgeTech data loggers with regulated conditions for temperature (40°C ±2) and relative humidity (75% ±5). For the time period of October 2021 to April 2022 the samples were located in the Accelerated Stability Chamber. The maximum temperature recorded was 40.05°C, the minimum temperature was 31.39°C, the average temperature was 39.94°C, and the Average Mean Kinetic Temperature was 39.94°C. The maximum relative humidity recorded was 81.4%, the minimum relative humidity was 62.2%, and the average relative humidity was 75.3%. Maximum and minimum values that are outside limits for temperature and humidity are due to opening the door of the chamber as explained in Temperature and Humidity Monitoring Assessments for the chambers. Section 5 will include any excursions from these conditions that resulted in an investigation.

4.2. For this study the samples were exposed to accelerated conditions in the Accelerated Stability Chamber (Temperature: 40°C ±2 and Relative Humidity: 75% ±5), which are harsher in regards to temperature and humidity than the recommended storage conditions, which for this product would have been the Real Time Stability Chamber (Temperature: 25°C ±2°C and Relative Humidity: 60% ±5%).

5. INVESTIGATIONS:

5.1. BLI21-36: This laboratory investigation documents the OOS Assay results for samples GALP-0121-00004-PV T=2 P/P and Labline. The original results for these samples were OOS low. For both samples, the results of six retests were within specification and that average was used as the reported value. The initial OOS low results were invalidated.

5.2. BLI22-02: This laboratory investigation documents an OOS Appearance of Solution result for GALP-0121-00007-PV T=3 P/P Accelerated. The original result for this sample was OOS with a result that exceeded the specification of ≤ 3 NTU and could not be considered a clear solution which would result in a passing test. The result of the investigation determined that a contamination issue during sample preparation was the root cause. An average of six retests were used to determine the final result for this sample time interval to be within specification, and be considered a passing test.

6. LOT EVALUATION:

TABLE 2A: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00004-PV P/P	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	100.01	100.66	99.26	98.61	98.86	98.52	99.51
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.43	80.49	80.17	80.51	80.42	80.45	80.47
	KF Water	≤ 1.0%	0.15	0.14	0.40	0.11	0.12	0.14	0.13
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.08	0.08	0.08	0.08	0.09
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	<0.6	<0.6	<0.6	<0.6	<0.6
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.14	0.08	0.08	0.08	0.08	0.09

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2B: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00004-PV Labline	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	100.01	99.67	99.23	98.28	98.53	98.66	98.84
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.43	80.51	80.45	80.53	80.45	80.39	80.47
	KF Water	≤ 1.0%	0.15	0.14	0.22	0.03	0.12	0.12	0.20
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.08	0.08	0.07	0.08	0.09
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	<0.6	<0.6	<0.6	<0.6	<0.6
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.14	0.08	0.08	0.07	0.08	0.09

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2C: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00005-PV P/P	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	98.69	99.22	100.36	98.50	98.97	99.19	99.03
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.49	80.52	80.33	80.45	80.52	80.48	80.48
	KF Water	≤ 1.0%	0.19	0.19	0.29	0.16	0.15	0.15	0.13
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.10	0.09	0.09	0.09	0.09	0.09
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	<0.6	<0.6	0.05	0.05	0.05	0.05
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	0.06	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.15	0.10	0.08	0.20	0.14	0.14	0.14

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2D: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00005-PV Labline	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	98.69	99.40	101.04	98.52	[4]97.98	98.43	99.57
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.49	80.33	80.42	80.42	80.38	80.44	80.21
	KF Water	≤ 1.0%	0.19	0.22	0.41	0.18	0.09	0.23	0.13
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.10	0.09	0.09	0.09	0.09	0.09
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	<0.6	<0.6	<0.6	<0.6	<0.6
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	0.06	< 1.0	< 1.0	< 1.0
	[5]Total Organic Impurities	≤ 1.0%	0.15	0.15	0.09	0.15	0.09	0.09	0.09

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Value meets specification (98.0%)
[5]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2E: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00006-PV P/P	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	98.57	98.11	99.99	98.59	98.60	98.78	99.62
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.41	80.42	80.50	80.49	80.46	80.44	80.47
	KF Water	≤ 1.0%	0.23	0.32	0.49	0.20	0.17	0.28	0.16
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.11	0.10	0.09	0.10	0.10	0.10	0.10
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	0.05	<0.6	0.05	<0.6	0.05
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	0.12	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.16	0.16	0.14	0.22	0.15	0.10	0.15

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2F: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00006-PV Labline	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	98.57	99.31	100.21	98.61	98.79	98.43	99.71
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.41	80.48	80.56	80.48	80.53	80.39	80.42
	KF Water	≤ 1.0%	0.23	0.23	0.28	0.21	0.16	0.28	0.16
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.11	0.10	0.09	0.10	0.09	0.10	0.10
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	0.05	0.05	<0.6	0.05	0.05
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	0.14	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.16	0.15	0.14	0.34	0.09	0.14	0.15

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

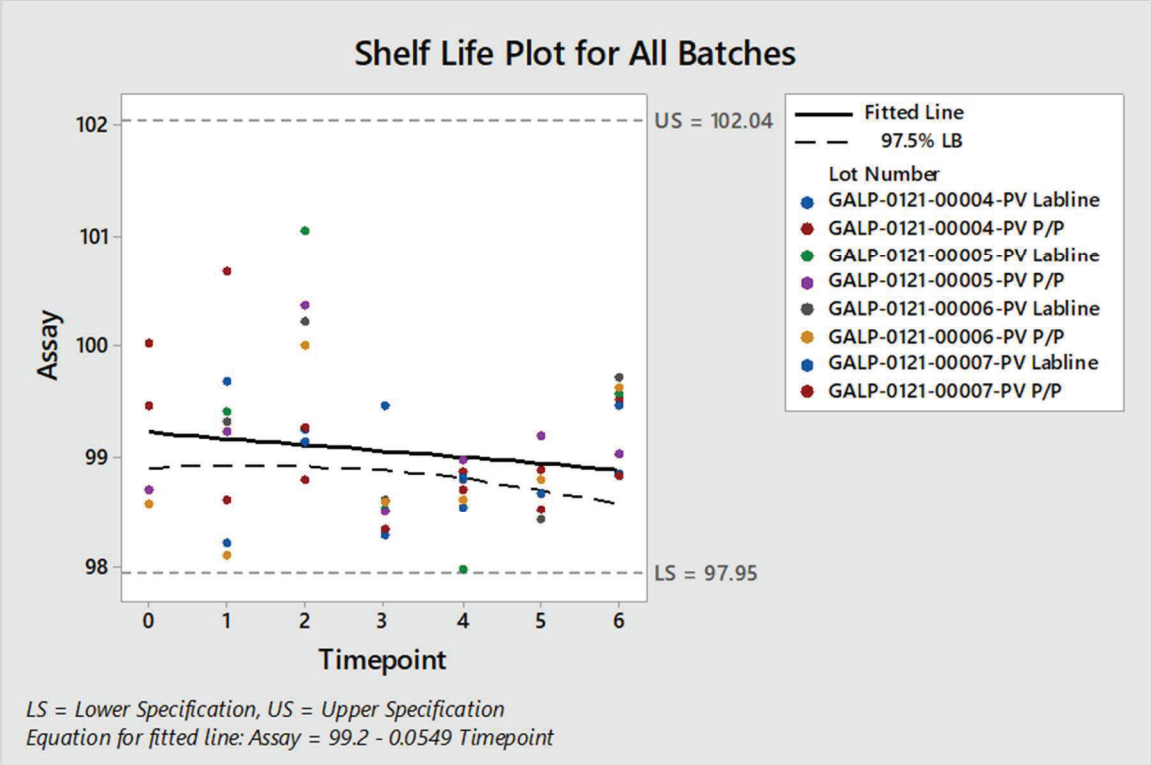
TABLE 2G: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00007-PV P/P	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	99.46	98.60	98.78	98.33	98.69	98.87	98.83
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.38	80.32	80.42	80.45	80.42	80.36	80.48
	KF Water	≤ 1.0%	0.11	0.20	0.18	0.18	0.16	0.17	0.18
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.08	0.10	0.07	0.07	0.06	0.07	0.06
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	0.05	0.05	0.05	0.05	<0.6
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	0.12	< 1.0	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.12	0.15	0.23	0.11	0.11	0.12	0.11

[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

TABLE 2H: ACCELERATED STABILITY ANALYSES									
Lot Number	**Analysis**	**Specification**	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6**
GALP-0121-00007-PV Labline	[1]Appearance	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WCP	WCP
	Acidity - Alkalinity	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	Assay	98.0 – 102.0%	99.46	98.21	99.13	99.46	98.81	98.87	99.46
	Appearance of Solution	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test	Passes Test
	[2]ID A (UATR)	Conforms to Standard	CS	CS	CS	CS	CS	CS	CS
	[3]ID B (HPLC)	Corresponds to Standard	CTS	CTS	CTS	CTS	CTS	CTS	CTS
	Specific Optical Rotation	+78.0° to +81.5° at 20°C	80.38	80.35	80.39	80.57	80.48	80.50	80.50
	KF Water	≤ 1.0%	0.11	0.27	0.19	0.19	0.17	0.22	0.17
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.08	0.07	0.06	0.07	0.07	0.07	0.07
	Galacturonic Acid	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dextrose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Tagatose	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Dulcitol	≤ 0.6%	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6	< 0.6
	Arabinose	≤ 0.6%	0.05	0.05	0.05	0.05	<0.6	<0.6	<0.6
	Unspecified (Single)	≤ 1.0%	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0	< 1.0
	[4]Total Organic Impurities	≤ 1.0%	0.12	0.12	0.11	0.12	0.07	0.07	0.07

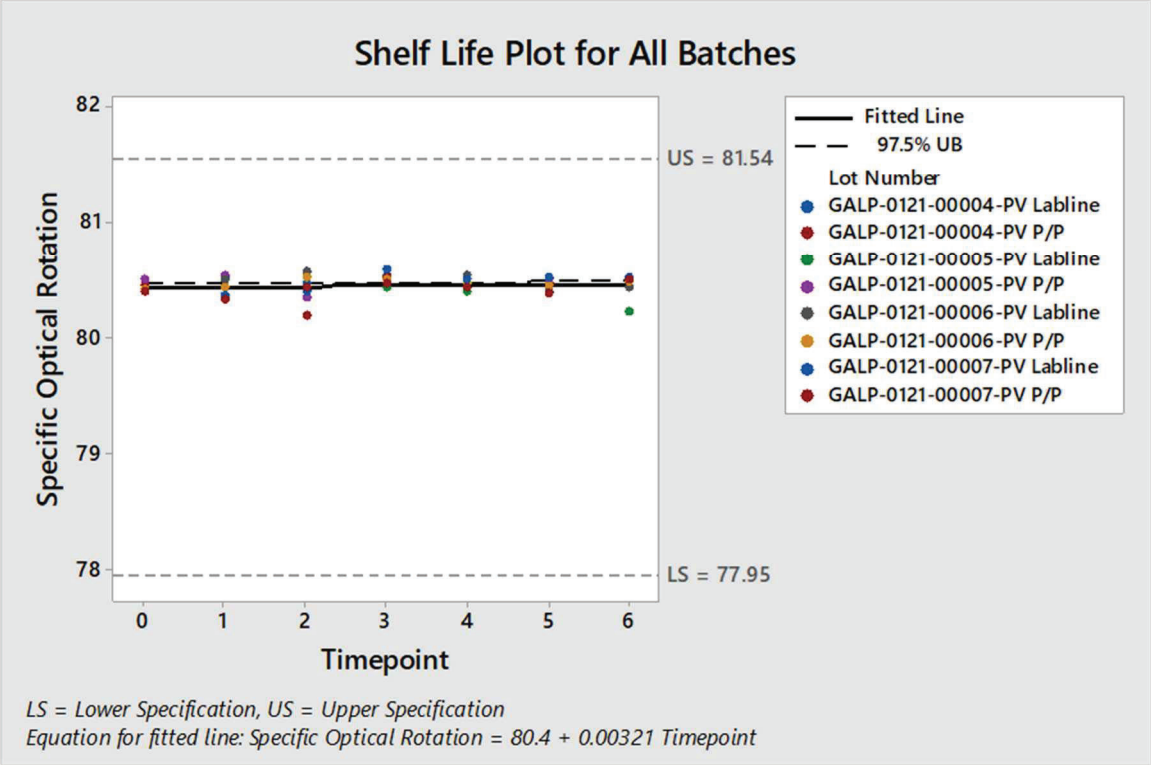
[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported as less than the specification.

GRAPH 1: ASSAY



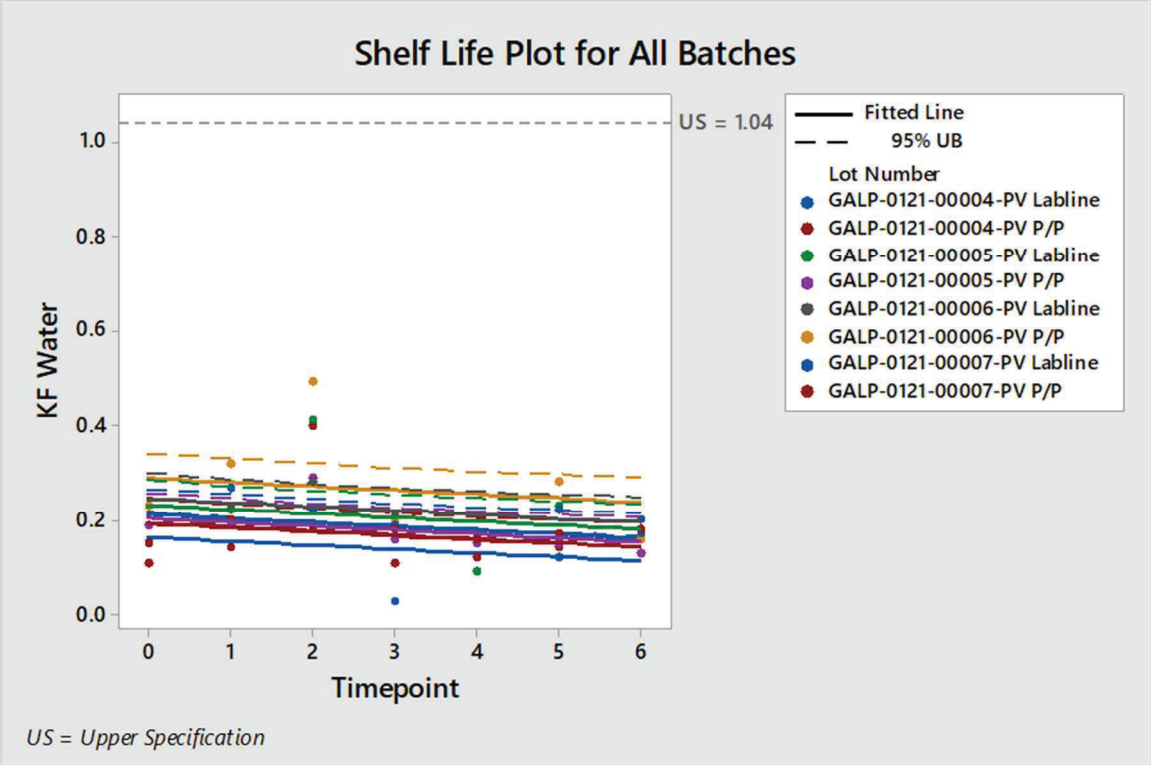
The No Shelf-Life was able to be determined for Assay, as the mean response slope is not significantly different from zero using 95% confidence. There is no impact to the product or currently assigned retest period of this material.

GRAPH 2: SPECIFIC OPTICAL ROTATION



The 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 3: KF WATER



The No Shelf-Life was able to be determined for 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:

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 date may be proposed for up to 1.5x, where x is the period covered by accelerated data, but should be no more than 6 months beyond for accelerated conditions. Accelerated Stability Data displayed in this report along with the predicted shelf-life plots would support a retest date of 9 months for Galactose manufactured at BioSpectra in the Bangor, PA facility.

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 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.

8.2. 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.

8.2.1. 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.

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