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D-GALACTOSE, PLANT DERIVED 2021 VALIDATION 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 twenty-four (24) months of real-time stability in October 2023 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. Endotoxin and microbial content were added at the 12-month timepoint. Results from all analyses are summarized in Table 2A through 2H.

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 October 2023 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 25.46°C, and the Average Mean Kinetic Temperature was 25.46°C. The maximum relative humidity recorded was 72.40%, the minimum relative humidity was 31.3%, and the average relative humidity was 61.3%. 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.

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. BDI22-61: This discrepancy documents missing data points from the download of the MadgeTech temperature loggers between 1/28/22 and 2/09/22. The logger was reset and started to work. No known reason could be identified as to why the logger stopped recording. There is no impact to the stability samples being stored in the chamber as the analog chart recorders showed no temperature deviations.

5.6. BDI22-138: This discrepancy documents an out of specification humidity readings. The out of specification humidity result was 50.8% and lasted for over 4 hours. This was due to a valve that regulates the humidity being turned off. There is no impact to the stability samples because the excursion was brief and lasted less than 5 hours.

5.7. BDI22-143: This discrepancy investigation documents the observed deviation in the Real Time Stability Chamber in November 2021 for missing data points. The root cause was identified as expired batteries in the MadgeTech temperature loggers. There is no impact to the stability samples being stored in the chamber as the analog chart recorders showed no temperature deviations.

6. LOT EVALUATION:

TABLE 2A: GALP-0121-00004-PV P/P

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	100.0	98.1	98.7	100.6	99.1	99.4	99.6			
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	80.55	80.55	80.34	80.71	80.80			
Endotoxins	≤2.5 EU/g	<1.00	Not tested	Not tested	Not tested	<1.00	<1.00	<1.00			
Microbial content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.15	0.14	0.25	0.15	0.13	0.02	0.15			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.08	0.08	0.08	0.09	0.10			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Arabinose	≤ 0.6%	0.05	<0.05	<0.05	<0.05	<0.05	0.05	0.05			
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	0.13	0.13	0.12	0.12	0.15	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.
[5] WP = White Powder

TABLE 2B: GALP-0121-00004-PV LABLINE

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	100.0	99.0	99.4	99.0	99.3	99.7	99.6			
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	80.41	80.56	80.48	80.41	80.53	80.67			
KF Water	≤ 1.0%	0.15	0.13	0.19	0.16	0.14	0.13	0.17			
Endotoxins	≤2.5 EU/g	<1.00	Not tested	Not tested	Not tested	<1.00	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.09	0.08	0.08	0.09	0.10			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Arabinose	≤ 0.6%	0.05	<0.05	<0.05	<0.05	<0.05	0.06	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
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	0.13	0.13	0.12	0.12	0.15	0.10			

[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.
[5] WP = White Powder

TABLE 2C: GALP-0121-00005-PV P/P

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1, 5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	98.7	98.7	99.9	98.7	98.5	99.5	98.7			
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	80.51	80.47	80.53	80.39	80.81	80.86			
Endotoxins	≤2.5 EU/g	<0.7	Not tested	Not tested	Not tested	<1.26	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.19	0.22	0.13	0.21	0.21	0.22	0.22			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.09	0.09	0.05	0.05	0.10	0.10			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Arabinose	≤ 0.6%	0.05	0.05	0.05	0.05	<0.05	0.05	0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Unspecified (Single)	≤ 1.0%	<1.0	0.06	<1.0	<1.0	<1.0	<1.0	<1.0			
[4]Total Organic Impurities	≤ 1.0%	0.15	0.19	0.14	0.13	0.13	0.15	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.
[5] WP = White Powder

TABLE 2D: GALP-0121-00005-PV LABLINE

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	98.7	98.9	100.0	98.7	98.3	99.3	99.2			
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	80.38	80.57	80.65	80.43	80.71	80.78			
Endotoxins	≤2.5 EU/g	<0.7	Not tested	Not tested	Not tested	<1.00	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.19	0.19	0.16	0.21	0.26	0.18	0.22			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.10	0.10	0.09	0.08	0.08	0.10	0.11			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Arabinose	≤ 0.6%	0.05	<0.05	0.05	<0.05	<0.05	0.05	0.06			
Unspecified (Single)	≤ 1.0%	<1.0	0.16	<1.0	<1.0	<1.0	<1.0	<1.0			
[4]Total Organic Impurities	≤ 1.0%	0.15	0.30	0.14	0.13	0.12	0.15	0.17			

[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.
[5] WP = White Powder

TABLE 2E: GALP-0121-00006-PV P/P

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	98.6	98.5	98.8	98.6	98.0	99.4	99.0			
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	80.49	80.43	80.44	80.45	81.02	80.73			
Endotoxins	≤2.5 EU/g	<0.5	Not tested	Not tested	Not tested	<0.994	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.23	0.22	0.14	0.21	0.18	0.24	0.31			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.11	0.10	0.10	0.08	0.09	0.11	0.12			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Arabinose	≤ 0.6%	0.05	0.05	0.05	0.05	0.05	0.06	0.06			
Unspecified (Single)	≤ 1.0%	<1.0	0.06	<1.0	<1.0	<1.0	<1.0	<1.0			
[4]Total Organic Impurities	≤ 1.0%	0.16	0.20	0.15	0.13	0.14	0.17	0.17			

[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.
[5] WP = White Powder

TABLE 2F: GALP-0121-00006-PV LABLINE

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	98.6	98.9	98.6	99.0	98.1	99.4	98.9			
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	80.45	80.58	80.39	80.18	80.71	80.92			
Endotoxins	≤2.5 EU/g	<0.5	Not tested	Not tested	Not tested	<0.993	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.23	0.21	0.17	0.24	0.23	0.24	0.28			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.11	0.10	0.10	0.08	0.09	0.10	0.12			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Arabinose	≤ 0.6%	0.05	0.05	0.05	0.05	0.05	0.05	0.05			
Unspecified (Single)	≤ 1.0%	<1.0	0.05	<1.0	<1.0	<1.0	<1.0	<1.0			
[4]Total Organic Impurities	≤ 1.0%	0.16	0.19	0.15	0.13	0.14	0.15	0.17			

[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.
[5] WP = White Powder

TABLE 2G: GALP-0121-00007-PV P/P

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,6]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	99.5	[4]97.9	99.4	99.1	99.3	99.6	99.4			
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	80.47	80.47	80.34	80.60	80.51	80.82			
Endotoxins	≤2.5 EU/g	<0.5	Not tested	Not tested	Not tested	<1.00	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.11	0.20	0.24	0.22	0.19	0.20	0.21			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.08	0.07	0.06	0.06	0.06	0.06	0.08			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Arabinose	≤ 0.6%	0.05	<0.05	0.05	<0.05	<0.05	0.05	0.05			
Unspecified (Single)	≤ 1.0%	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0			
[5]Total Organic Impurities	≤ 1.0%	0.12	0.07	0.11	0.10	0.10	0.11	0.13			

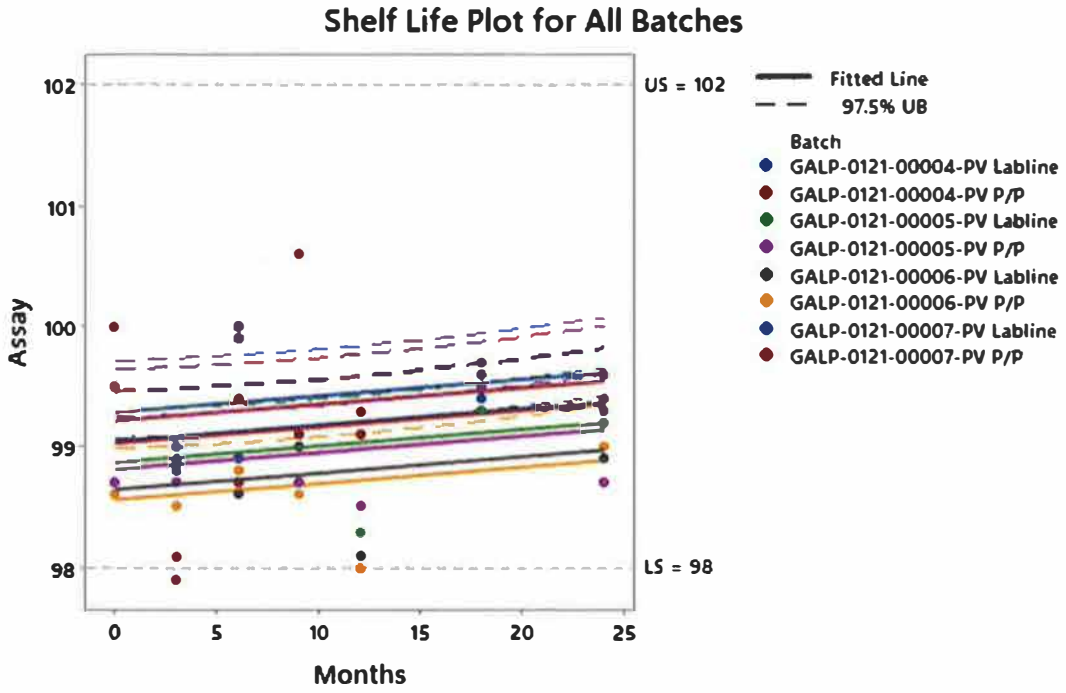
[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder
[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Result is OOS, refer to BLI22-06
[5]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported,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

TABLE 2H: GALP-0121-00007-PV LABLINE

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
[1,5]Appearance and Color	White to Off White Crystalline Powder	WCP	WCP	WCP	WCP	WCP	WP	WCP	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	Passes Test	Passes Test	Passes Test	Passes Test			
Assay	98.0 – 102.0%	99.5	98.8	98.9	99.1	99.3	99.4	99.3			
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	80.48	80.41	80.31	80.56	80.58	80.94			
Endotoxins	≤2.5 EU/g	<0.5	Not tested	Not tested	Not tested	<0.993	<1.00	<1.00			
Microbial Content	TAMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	TYMC ≤100 CFU/g	<10	Not tested	Not tested	Not tested	<10	<10	<10			
	Pseudomonas aeruginosa (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Salmonella aureus (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
	Escherichia coli (Absent)	Absent	Not tested	Not tested	Not tested	Absent	Absent	Absent			
KF Water	≤ 1.0%	0.11	0.20	0.13	0.23	0.20	0.20	0.21			
Lactose and 1,6-galactosyl-galactose	≤ 0.6%	0.08	0.07	0.06	0.06	0.06	0.06	0.08			
Galacturonic Acid	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dextrose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Tagatose	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			
Dulcitol	≤ 0.6%	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05			

Analysis	Specification	T_0	T_3	T_6	T_9	T_{12}	T_{18}	T_{24}	T_{36}	T_{48}	T_{60}
Arabinose	≤ 0.6%	0.05	0.05	<0.05	<0.05	<0.05	0.06	0.05			
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	0.10	0.10	0.13	0.13			

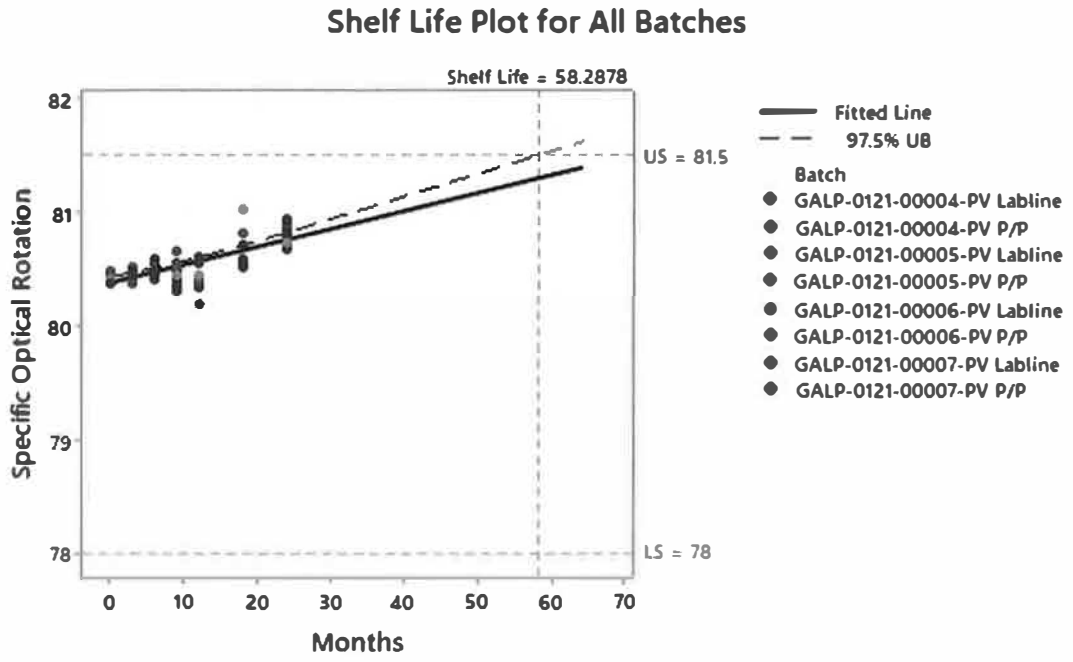
[1]WCP = White to Off White Crystalline Powder, White Crystalline Powder[2]CS = Conforms to Standard
[3]CTS = Corresponds to Standard
[4]Total Organic Impurities: The Method LOQ for organic impurities is ≤0.05%. Results for each impurity above the LOQ will be reported, results below the LOQ will be reported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



LS = Lower Specification, US = Upper Specification

GRAPH 1: ASSAY

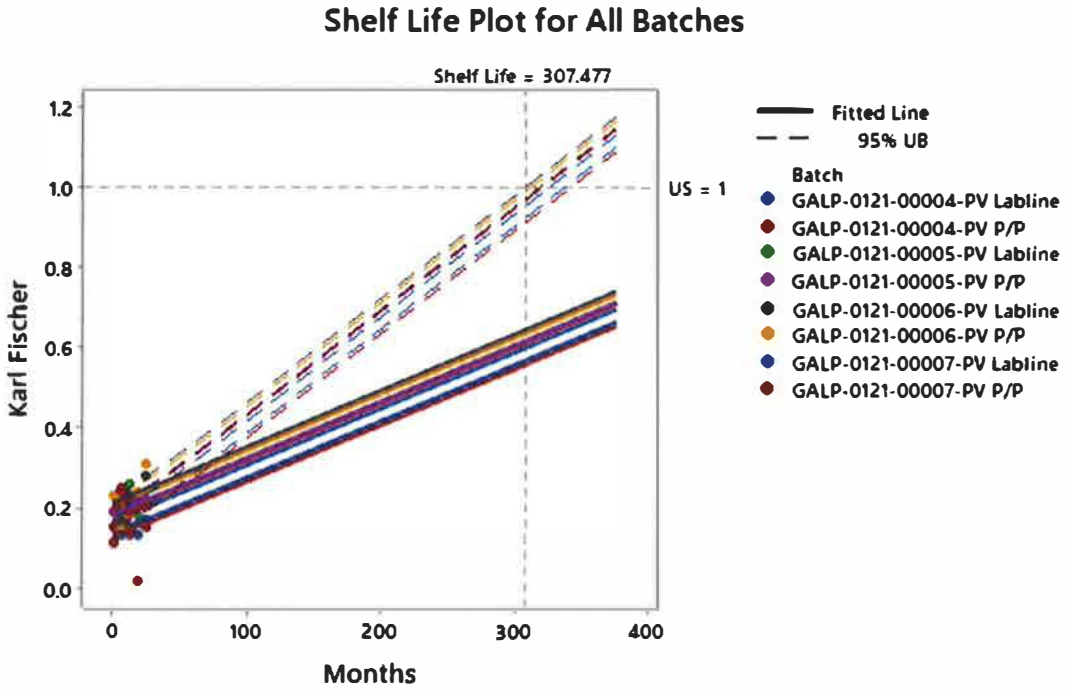
No Shelf-Life was able to be determined for Assay, as the mean response slope is not significantly different from zero using 95% confidence. There is no impact to the product or currently assigned retest period of this material as all results met the predetermined specifications at T=24 months.



LS = Lower Specification, US = Upper Specification
Equation for fitted line: Specific Optical Rotation = 80.4 + 0.0158 Months

GRAPH 2: SPECIFIC OPTICAL ROTATION

The predicted Shelf-Life for Specific Optical Rotation was determined to be 58.2878 months as of the T=24-month time interval. There is no impact to the product or currently assigned retest period of this material.



US = Upper Specification

GRAPH 3: KARL FISCHER (WATER)

The predicted Shelf-Life for Karl Fischer (Water) was determined to be 307.477 months as of the T=24-month time interval. There is no impact to the product or currently assigned retest period of this material, as this is beyond the end of the current study.

7. CONCLUSION:

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 up to T=24 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. The Assay results were statistically evaluated to determine if the T=3 results for Assay is an outlier, based on the 24 month data the result of the statistical evaluation the 97.9 assay result was not indicative of the batch as all other time points met the specification requirements and the shelf-life plot, Graph 1 showed acceptable shelf-life after the 24 month timepoint.

In regards to the real time stability study for Galactose 2021 validation lots, all other data met the specifications set forth in the stability testing program for the lot stored at the recommended real time condition. In accordance with ICH Q1E, the retest date may be proposed for up to 2x, where x is the period covered by long-term stability data, but should be no more than 12 months beyond for real time conditions (warehouse conditions of 15 – 30°C). The real time stability study data, along with the predicted shelf-life plots, supports a retest date of 24 months and an expiration date of 36 months may be assigned upon request for D-Galactose, Plant Derived material 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.