

BIOSPECTRA

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

GALACTOSE (PLANT DERIVED)

SPECIFICATION SHEET

BIO EXCIPIENT GRADE, LBLE / GA32XX

$C_6H_{12}O_6$ * F.W. 180.16 g/mol * CAS# 59-23-4

ANALYSIS	SPECIFICATIONS	
Acidity	Passes Test	
Acidity or Alkalinity	Passes Test	
Appearance	White to almost white, crystalline powder	
Appearance of Solution	Passes Test	
Assay	97.0 – 102.0	
Barium	Passes Test	
Endotoxins	≤ 2.5 EU/g	
Glucose	≤ 0.1%	
Identification A	Passes Test	
Identification B	Passes Test	
Impurities A and B	≤ 1.0%	
Lead	≤ 0.5 ppm	
Proteins	≤ 0.1 mg/ml	
Microbial Content	<i>Escherichia coli</i>	Absent
	<i>Pseudomonas aeruginosa</i>	Absent
	<i>Salmonella species</i>	Absent
	<i>Staphylococcus aureus</i>	Absent
	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Purity (HPLC)	≥ 99%	
Analysis	Specifications	
Residual Ethanol	≤ 500 ppm	
Residual Isopropanol	≤ 5000 ppm	
Residual Methanol	≤ 100 ppm	
Residual Methyl Isobutyl Ketone	≤ 500 ppm	

ANALYSIS	SPECIFICATIONS
Residue on Ignition	< 0.1%
Solution Clarity (300 mg/mL)	Passes Test
Specific Rotation	+78.0° to +81.5.0 °
Sulfated Ash	≤ 0.1%
Total Impurities	≤ 2.0%
Unspecified Impurities	≤ 0.3% each
Water	< 0.1%

DRAFT