

BIOSPECTRA

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

D-GALACTOSE SPECIFICATION SHEET BIO EXCIPIENT GRADE / GA3250

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

Meets or Exceeds EP/BP and NF Specifications

EP COMPENDIA		
ANALYSIS		SPECIFICATIONS
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
Identification A		Passes Test
Identification B		Passes Test
Identification C		Passes Test
Impurities A and B		≤ 1.0%
Lead		≤ 0.5 ppm
Microbial Content	TAMC	≤ 100 CFU/g
Proteins		≤ 0.1 mg/ml
Sulfated Ash		≤ 0.1%
Total Impurities		≤ 2.0%
Unspecified Impurities		≤ 0.3% each
Water		≤ 1.0%

NF COMPENDIA		
ANALYSIS	SPECIFICATIONS	
Acidity	Passes Test	
Appearance of Solution	Passes Test	
Barium	Passes Test	
Identification A	Passes Test	
Identification B	Passes Test	
Limit of Lead	≤ 0.5 ppm	
Microbial Content	<i>Escherichia coli</i>	Absent
	<i>Pseudomonas aeruginosa</i>	Absent
	<i>Salmonella species</i>	Absent
	<i>Staphylococcus aureus</i>	Absent
	TAMC	≤ 1000 CFU/g
	TYMC	≤ 100 CFU/g
Residue on Ignition	≤ 0.1%	
Optical Rotation, Specific Rotation	+78.0° to +81.5 °	
Water	≤ 1.0%	

ANALYSIS	SPECIFICATIONS
Endotoxins	≤ 2.5 EU/g
Glucose	≤ 0.1%
Residual Ethanol	≤ 500 ppm
Residual Isopropanol	≤ 5000 ppm
Residual Methanol	≤ 100 ppm
Residual Methyl Isobutyl Ketone	≤ 500 ppm