

BIOSPECTRA

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

D-GALACTOSE SPECIFICATION SHEET BIO EXCIPIENT GRADE / GA3250

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

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	$\leq 1.0\%$
Lead	≤ 0.5 ppm
Microbial Content TAMC	≤ 100 CFU/g
Proteins	≤ 0.1 mg/ml
Sulfated Ash	$\leq 0.1\%$
Total Impurities	$\leq 2.0\%$
Unspecified Impurities	$\leq 0.3\%$ each
Water	$\leq 1.0\%$

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%	
Specific Rotation	+78.0° to +81.5 °	
Water	≤ 1.0%	

GA3250 D-Galactose Bio Excipient Specifications

ANALYSIS	SPECIFICATIONS
Endotoxins	≤ 2.5 EU/g
Glucose	$\leq 0.1\%$
Purity (HPLC)	$\geq 99\%$
Residual Ethanol	≤ 500 ppm
Residual Isopropanol	≤ 5000 ppm
Residual Methanol	≤ 100 ppm
Residual Methyl Isobutyl Ketone	≤ 500 ppm
Solution Clarity (300 mg/mL)	Passes Test