

## D-GALACTOSE, PLANT DERIVED BIOTECH, MEETS EP, NF, LBLE, GMP BIO PHARMA GRADE / GALP-4250

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

### Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

D-Galactose, plant derived, is intended for use upstream and downstream in biopharmaceutical and biotech manufacturing processes and products. BioSpectra's D-Galactose is manufactured to meet high purity specifications and low bioburden and endotoxin demands. This product is manufactured under full GMP conditions and meets multicompendial specifications.

### SPECIFICATIONS

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity	Acidity or Alkalinity (EP)	Passes Test
	Acidity (NF)	Passes Test
Appearance		White to almost white crystalline powder
Appearance of Solution (EP/NF)		Passes Test
Assay, Anhydrous Basis (EP/NF)		98.0% - 102.0%
Barium (NF)		Passes Test
Endotoxins		$\leq 2.5$ EU/g
Glucose		$\leq 0.1\%$
Identification A (EP/NF)		Conforms to Reference Standard
Identification B (EP/NF)		Passes Test
Identification C (EP/NF)		Passes Test
Limit of Lead (NF)		$\leq 0.5$ ppm
Microbial Content	TAMC (EP/NF)	$\leq 100$ CFU/g
	TYMC (NF)	$\leq 100$ CFU/g
	Escherichia coli (NF)	Absent
	Pseudomonas aeruginosa (NF)	Absent
	Salmonella species (NF)	Absent
	Staphylococcus aureus (NF)	Absent
Proteins (EP)		$\leq 0.1$ mg/mL
Optical Rotation, Specific Rotation (NF)		$+78.0^\circ$ to $+81.5^\circ$
Residue on Ignition (NF)		$\leq 0.1\%$
Sulfated Ash (EP)		$\leq 0.1\%$

Related Substances	Lactose and 1,6-galactosyl-galactose (NF)	≤ 0.6 %
	Galacturonic acid (NF)	≤ 0.6 %
	Dextrose (NF)	≤ 0.6 %
	Tagatose (NF)	≤ 0.6 %
	Dulcitol (NF)	≤ 0.6 %
	Arabinose (NF)	≤ 0.6 %
	Any Unspecified Impurity (EP/NF)	≤ 0.2 %
	Sum of Impurities A and B (EP)	≤ 1.0 %
	Total Impurities (EP/NF)	≤ 1.0 %
Residual Ethanol	≤ 500 ppm	
Residual Isopropanol	≤ 5000 ppm	
Residual Methanol	≤ 100 ppm	
Residual Methyl Isobutyl Ketone	≤ 500 ppm	
Water, KF (EP/NF)	≤ 1.0%	

### General Product Description:

Molecular Formula: C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>

Molecular Weight: 180.16 g/mol

CAS Number: 59-23-4

### D-Galactose Biotech:

- Appears as a white to near-white crystalline product
- Is manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: alpha-D-Galactose; Galactose

### Shelf Life Policy:

Three-year expiry from the date of manufacture.

### Storage and Shipping

#### Conditions:

Please refer to the SDS for storage and shipping conditions.

#### Package Size:

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg