

# D-GALACTOSE, PLANT DERIVED

## EP, NF, LBLE, GMP

CAS #: 59-23-4

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

F.W.: 180.16 g/mol

### GALP-4250

### BIO PHARMA GRADE

ANALYSIS	SPECIFICATIONS
Acidity or Alkalinity (EP/NF)	Passes Test
Appearance and Color	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
Endotoxin	< = 2.5 EU/g
Glucose	< = 0.1%
Identification A, IR (EP/NF)	Conforms to Reference Standard
Identification B (EP/NF)	Conforms to Reference Standard
Identification C (EP/NF)	Passes Test
Limit of Lead (NF)	< = 0.5 ppm
Microbial Content	TAMC (EP/NF) < = 100 CFU/g TYMC (NF) < = 100 CFU/g <i>Escherichia coli</i> (NF) Absent/g <i>Pseudomonas aeruginosa</i> (NF) Absent/g <i>Salmonella species</i> (NF) Absent/10g <i>Staphylococcus aureus</i> (NF) Absent/g
Proteins (EP)	< = 0.1 mg/mL
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%
Specific Optical Rotation, 20°C (NF)	+78.0° to +81.5°
Residue on Ignition / Sulfated Ash (NF/EP)	< = 0.1%
Residual Solvents	Ethanol < = 500 ppm Isopropanol < = 5000 ppm Methanol < = 100 ppm Methyl Isobutyl Ketone < = 500 ppm
Water, KF (EP/NF)	< = 1.0%

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

This is an ultra-high purity, reagent grade product, purified under cGMP conditions. 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 meets multicompendial specifications.

### General Product Description

- Appears as a white to almost white crystalline powder
- Manufactured in accordance with IPEC
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: D-Galactopyranose; alpha-D-Galactose
- Visit the product page on our website ([www.biospectra.us](http://www.biospectra.us)) for additional information, supporting regulatory documents, and CoAs.

### Storage and Shipping Conditions

Refer to SDS.

### Standard Shelf Life Policy

Each Certificate of Analysis will contain a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

### Package Sizes

1kg, 5kg, 10kg, 25kg, 50kg

### Standard Lead Time

2-4 weeks

### Country of Origin: USA

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