

## D-GALACTOSE

PLANT DERIVED, EP, NF, LBLE, ULTRA LOW LEI, 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-3252**

**BIO EXCIPIENT GRADE**

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity	Acidity or Alkalinity (EP) Acidity (NF)	Passes Test Passes Test
Appearance		White to almost white, crystalline or finely granulated powder
Appearance of Solution (EP/NF)		Passes Test
Assay, Anhydrous Basis HPLC (EP/NF)		98.0 – 102.0%
Endotoxins		≤ 1.0 EU/g
Glucose		≤ 0.2%
Identification A (EP/NF)		Conforms to Reference
Identification B (EP/NF)		Passes Test
Identification C (EP/NF)		Passes Test
Microbial Content	TAMC (EP/NF)	≤ 50 CFU/g
	TYMC (NF)	≤ 50 CFU/g
	<i>Escherichia coli</i> (NF)	Absent
	<i>Pseudomonas aeruginosa</i> (NF)	Absent
	<i>Salmonella species</i> (NF)	Absent
	<i>Staphylococcus aureus</i> (NF)	Absent
Proteins (EP)		≤ 0.1 mg/mL
Purity by HPLC		≥ 99.0%
Related Substances	Lactose and 1,6-galactosyl-galactose (NF)	≤ 0.3%
	Galacturonic acid (NF)	≤ 0.2%
	Dextrose (NF)	≤ 0.2%
	Tagatose (NF)	≤ 0.2%
	Dulcitol (NF)	≤ 0.2%
	Arabinose (NF)	≤ 0.3%
	Any Unspecified Impurity (EP/NF)	≤ 0.2%
	Sum of Impurities A and B (EP)	≤ 1.0%
	Total Impurities (EP/NF)	≤ 0.8%
Optical Rotation, Specific Rotation @ 20°C (NF)		+78.0° to +81.5°
Residue on Ignition (NF)		≤ 0.05%
Sulfated Ash (EP)		≤ 0.1%
Residual Ethanol		≤ 200 ppm
Residual Isopropanol		≤ 5000 ppm
Residual Methanol		≤ 200 ppm
Residual Methyl Isobutyl Ketone		≤ 500 ppm
Water, KF (EP/NF)		≤ 1.0%

ANALYSIS		SPECIFICATIONS
Trace Metals	Aluminum (Al)	≤ 63 ppb
	Arsenic (As)	≤ 50 ppb
	Barium (Ba)	≤ 63 ppb
	Cadmium (Cd)	≤ 50 ppb
	Cobalt (Co)	≤ 50 ppb
	Chromium (Cr)	≤ 250 ppb
	Copper (Cu)	≤ 63 ppb
	Iron (Fe)	≤ 250 ppb
	Lead (Pb)	≤ 50 ppb
	Manganese (Mn)	≤ 63 ppb
	Molybdenum (Mo)	≤ 50 ppb
	Nickel (Ni)	≤ 50 ppb
	Selenium (Se)	≤ 50 ppb
	Vanadium (V)	≤ 63 ppb
	Zinc (Zn)	≤ 250 ppb

### Intended for Use in Pharma Mfg. Requiring ICH-Q7, Excipient Grade Quality & Compliance

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 near-white crystalline powder
- Manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in a hormone free and animal free environment
- 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/derivatives.
- Is not subject to genetic modification
- Synonyms: alpha-D-Galactose; Galactose
- Visit the product page on our website ([www.biospectra.us](http://www.biospectra.us)) for additional information, supporting regulatory documents, and CofAs.

### Storage and Shipping Conditions

Refer to SDS.

### Standard Shelf Life Policy

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

### Package Sizes

5kg, 10kg, 25kg, 50kg

### Minimum Order Quantity

25kg

### Standard Lead Time

If stock: 1-month / If no stock: 6-months

### Country of Origin: USA