

D-GALACTOSE

BIOTECH, PLANT DERIVED, EP, NF, LBLE, GMP

CAS #: 59-23-4

Formula: C₆H₁₂O₆

F.W.: 180.16 g/mol

GALP-4250

BIO PHARMA GRADE

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity	Acidity or Alkalinity (EP) Acidity (NF)	Passes Test 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		≤ 2.5 EU/g
Glucose		≤ 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)		≤ 0.5 ppm
Microbial Content	TAMC (EP/NF)	≤ 100 CFU/g
	TYMC (NF)	≤ 100 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
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%
	Optical Rotation, Specific Rotation (NF)	+78.0° to +81.5°
Residue on Ignition (NF)		≤ 1.0%
Sulfated Ash (EP)		≤ 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%

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

This is an ultra-high purity, GMP, Reagent grade product, purified under full 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 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) 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

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

Standard Lead Time

1-2 weeks

Country of Origin: USA

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