

D-GALACTOSE, 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 (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) TYMC (NF) Escherichia coli (NF) Pseudomonas aeruginosa (NF) Salmonella species (NF) Staphylococcus aureus (NF)	< = 100 CFU/g < = 100 CFU/g Absent/g Absent/g Absent/10g Absent/g
Proteins (EP)	< = 0.1 mg/mL	
Related Substances	Lactose and 1,6-galactosyl-galactose (NF) Galacturonic acid (NF) Dextrose (NF) Tagatose (NF) Dulcitol (NF) Arabinose (NF) Any Unspecified Impurity (EP/NF) Sum of Impurities A and B (EP) Total Impurities (EP/NF)	< = 0.6% < = 0.6% < = 0.6% < = 0.6% < = 0.6% < = 0.2% < = 1.0% < = 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 Isopropanol Methanol Methyl Isobutyl Ketone	< = 500 ppm < = 5000 ppm < = 100 ppm < = 500 ppm
Water, KF (EP/NF)	< = 1.0%	

General Product Overview

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.

Industry Application

Suitable for use in biological and biotech chemical process applications from R&D through scale cGMP production.

Key Product Features

- 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

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has 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

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

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