

D-GALACTOSE

PLANT DERIVED, MEETS EP/NF, BET*, LEI**, GMP

CAS #: 59-23-4

Formula: C₆H₁₂O₆

F.W.: 180.16 g/mol

GALP-3351

BIO EXCIPIENT 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
TAMC (EP/NF)	< = 100 CFU/g
TYMC (NF)	< = 100 CFU/g
Microbial Content	
Escherichia coli (NF)	Absent/g
Pseudomonas aeruginosa (NF)	Absent/g
Salmonella species (NF)	Absent/10g
Staphylococcus aureus (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%

ANALYSIS	SPECIFICATIONS
Specific Optical Rotation, 20°C (NF)	+78.0° to +81.5°
Residue on Ignition / Sulfated Ash (NF/EP)	< = 0.1%
Trace Metals	
Aluminum (Al)	< = 0.400 ppm
Cadmium (Cd)	< = 0.010 ppm
Cobalt (Co)	< = 0.050 ppm
Chromium (Cr)	< = 0.050 ppm
Copper (Cu)	< = 0.025 ppm
Iron (Fe)	< = 0.200 ppm
Manganese (Mn)	< = 0.025 ppm
Molybdenum (Mo)	< = 0.050 ppm
Nickel (Ni)	< = 0.050 ppm
Selenium (Se)	< = 0.050 ppm
Vanadium (V)	< = 0.050 ppm
Zinc (Zn)	< = 0.200 ppm
Water, KF (EP/NF)	< = 1.0%
Residual Solvents	
Ethanol	< = 500 ppm
Isopropanol	< = 5000 ppm
Methanol	< = 100 ppm
Methyl Isobutyl Ketone	< = 500 ppm

*Bioburden and Endotoxin Tested

**Low Elemental Impurities

Refer to page 2 for additional product details.

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General Product Overview

D-Galactose, plant derived is intended for use upstream and downstream in biological drug manufacturing processes. For this purpose, BioSpectra has categorized our product as an excipient though one of the primary functions is to be used as a nutrient in mammalian cell culture media. Given the sensitivity of these cells in regard to growth, BioSpectra's D-Galactose is manufactured to meet high purity specifications and low bioburden and endotoxin demands.

Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of D-Galactose, GALP-3351 is performed at BioSpectra's Bangor, PA facility.
- Appears as a white to almost white crystalline powder
- Manufactured in accordance with ICH Q7
- 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.
- It is not subject to genetic modification.
- Synonyms: D-Galactopyranose

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

5kg, 10kg, 25kg, 50kg

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

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