

## D-GALACTOSE

PLANT DERIVED, EP, NF, LBLE, ULTRA LOW LEI, GMP

CAS #: 59-23-4

Formula:  $C_6H_{12}O_6$

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
Microbial Content	TAMC (EP/NF) < = 100 CFU/g
	TYMC (NF) < = 100 CFU/g
	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

**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 pail, 10kg pail, or 25kg pail and 50kg drum

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

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