

D-GALACTOSE

PLANT DERIVED, EP, NF, LBLE, ULTRA LOW LEI, GMP
CAS #: 59-23-4
Formula: C₆H₁₂O₆
F.W.: 180.16 g/mol
GALP-3252
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		< = 1.0 EU/g
Glucose		< = 0.2%
Identification A, IR (EP/NF)		Conforms to Reference Standard
Identification B (EP/NF)		Conforms to Reference Standard
Identification C (EP/NF)		Passes Test
Microbial Content	TAMC (EP/NF)	< = 50 CFU/g
	TYMC (NF)	< = 50 CFU/g
	Escherichia coli (NF)	Absent/g
	Pseudomonas aeruginosa (NF)	Absent/g
	Salmonella species (NF)	Absent/10g
	Staphylococcus aureus (NF)	Absent/g
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%

ANALYSIS		SPECIFICATIONS
Proteins (EP)		< = 0.1 mg/mL
Purity		> = 99%
Specific Optical Rotation, 20°C (NF)		+78.0° to +81.5°
Residue on Ignition/ Sulfated Ash (EP/NF)		< = 0.05%
Trace Metals	Aluminum (Al)	< = 0.063 ppm
	Arsenic (As)	< = 0.050 ppm
	Barium (Ba)	< = 0.063 ppm
	Cadmium (Cd)	< = 0.050 ppm
	Cobalt (Co)	< = 0.050 ppm
	Chromium (Cr)	< = 0.250 ppm
	Copper (Cu)	< = 0.063 ppm
	Iron (Fe)	< = 0.250 ppm
	Lead (Pb) (NF)	< = 0.050 ppm
	Manganese (Mn)	< = 0.063 ppm
	Molybdenum (Mo)	< = 0.050 ppm
	Nickel (Ni)	< = 0.050 ppm
	Selenium (Se)	< = 0.050 ppm
Water, KF (EP/NF)	Vanadium (V)	< = 0.063 ppm
	Zinc (Zn)	< = 0.250 ppm
Residual Solvents		< = 1.0%
Residual Solvents	Ethanol	< = 200 ppm
	Isopropanol	< = 5000 ppm
	Methanol	< = 200 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-3252 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.
- 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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