

D-GALACTOSE

PLANT DERIVED, EP, NF, LBLE, GMP

CAS #: 59-23-4

 Formula: C₆H₁₂O₆

F.W.: 180.16 g/mol

GALP-3250
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
Related Substances	Staphylococcus aureus (NF) Absent/g
	Proteins (EP) < = 0.1 mg/mL
	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%
Specific Optical Rotation, 20°C (NF)	+78.0° to +81.5°
Residue on Ignition / Sulfated Ash (NF/EP)	< = 0.1%
Residual Solvents	Ethanol < = 500 ppm
	Isopropanol < = 5000 ppm
	Methanol < = 100 ppm
	Methyl Isobutyl Ketone < = 500 ppm
Water, KF (EP/NF)	< = 1.0%

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 regarding growth, BioSpectra's D-Galactose is manufactured to meet high purity specifications as well as 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-3250 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, 10kg, or 25kg pail or 50kg drum

Standard Lead Time

Up to 6-months

Minimum Order Quantity

25kg

Country of Origin: USA

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