

D-GALACTOSE, PLANT DERIVED BIOTECH, MEETS EP, NF, LBLE, GMP BIO PHARMA GRADE / GALP-4250

$C_6H_{12}O_6$ Δ F.W. 180.16 g/mol Δ CAS# 59-23-4

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

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 is manufactured under full GMP conditions and meets multicompendial specifications.

SPECIFICATIONS

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity	Acidity or Alkalinity (EP)	Passes Test
	Acidity (NF)	Passes Test
Appearance		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
Endotoxins		≤ 2.5 EU/g
Glucose		$\leq 0.1\%$
Identification A (EP/NF)		Conforms to Reference Standard
Identification B (EP/NF)		Passes Test
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
	Pseudomonas aeruginosa (NF)	Absent
	Salmonella species (NF)	Absent
	Staphylococcus aureus (NF)	Absent
Proteins (EP)		≤ 0.1 mg/mL
Optical Rotation, Specific Rotation (NF)		$+78.0^\circ$ to $+81.5^\circ$
Residue on Ignition (NF)		$\leq 0.1\%$
Sulfated Ash (EP)		$\leq 0.1\%$

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 %
Residual Ethanol		≤ 500 ppm
Residual Isopropanol		≤ 5000 ppm
Residual Methanol		≤ 100 ppm
Residual Methyl Isobutyl Ketone		≤ 500 ppm
Water, KF (EP/NF)		≤ 1.0%

General Product Description:

Molecular Formula: C₆H₁₂O₆

Molecular Weight: 180.16 g/mol

CAS Number: 59-23-4

D-Galactose Biotech:

- Appears as a white to near-white crystalline product
- Is manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: alpha-D-Galactose; Galactose

Shelf Life Policy:

Three-year expiry from the date of manufacture.

Storage and Shipping

Conditions:

Please refer to the SDS for storage and shipping conditions.

Package Size:

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg