

GALACTOSE (D) BIOTECH PLANT DERIVED, EP, NF, LBLE, GMP GALP-4250

$C_6H_{12}O_6$ F.W. 180.16 g/mol 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 (EP)		Passes Test
Appearance (EP)		White to almost white, crystalline powder
Appearance of Solution (EP)		Passes Test
Assay (EP)		97.0% - 102.0%
Barium (EP, NF)		Passes Test
Identification A (EP, NF)		Passes Test
Identification B (EP, NF)		Passes Test
Identification C (EP, NF)		Passes Test
Microbial Content (EP)	TAMC	≤ 100 CFU/g
Proteins (EP)		≤ 0.1 mg/ml
Related Substances (EP)	Impurities A and B	$\leq 1.0\%$
	Unspecified Impurities	$\leq 0.3\%$ each
	Total Impurities	$\leq 2.0\%$
Sulfated Ash (EP)		$\leq 0.1\%$
Water (EP, NF)		$\leq 1.0\%$
Acidity (NF)		Passes Test
Appearance of Solution (NF)		Passes Test
Assay (NF)		98.0% - 102.0%
Limit of Lead (NF)		≤ 0.5 ppm
Microbial Content (NF)	<i>Escherichia coli</i>	Absent
	<i>Pseudomonas aeruginosa</i>	Absent

	<i>Salmonella species</i>	Absent
	<i>Staphylococcus aureus</i>	Absent
	TAMC	≤ 1000 CFU/g
	TYMC	≤ 100 CFU/g
	Lactose and 1, 6-galactosyl-galactose	≤ 0.6%
	Galacturonic acid	≤ 0.6%
	Dextrose	≤ 0.6%
Related Substances (NF)	Tagatose	≤ 0.6%
	Dulcitol	≤ 0.6%
	Arabinose	≤ 0.6%
	Any Unspecified Impurity	≤ 0.2%
	Total Impurities	≤ 1.0%
Residue on Ignition (NF)		≤ 0.1%
Optical Rotation, Specific Rotation (NF)		+78.0° to +81.5°
Endotoxins		≤ 2.5 EU/g
Glucose		≤ 0.1%
Lead		≤ 0.5 ppm
Residual Ethanol		≤ 500 ppm
Residual Isopropanol		≤ 5000 ppm
Residual Methanol		≤ 100 ppm
Residual Methyl Isobutyl Ketone		≤ 500 ppm

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