

# D-GALACTOSE, PLANT DERIVED

EP, NF, LBLE, GMP

CAS #: 59-23-4

Formula: C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>

F.W.: 180.16 g/mol

**GALP-4250**

**BIO PHARMA 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<br>TYMC (NF) < = 100 CFU/g<br>Escherichia coli (NF) Absent/g<br>Pseudomonas aeruginosa (NF) Absent/g<br>Salmonella species (NF) Absent/10g<br>Staphylococcus aureus (NF) Absent/g  |
| Proteins (EP)                              | < = 0.1 mg/mL   |
| Related Substances                         | Lactose and 1,6-galactosyl-galactose (NF) < = 0.6%<br>Galacturonic acid (NF) < = 0.6%<br>Dextrose (NF) < = 0.6%<br>Tagatose (NF) < = 0.6%<br>Dulcitol (NF) < = 0.6%<br>Arabinose (NF) < = 0.6%<br>Any Unspecified Impurity (EP/NF) < = 0.2%<br>Sum of Impurities A and B (EP) < = 1.0%<br>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<br>Isopropanol < = 5000 ppm<br>Methanol < = 100 ppm<br>Methyl Isobutyl Ketone < = 500 ppm   |
| Water, KF (EP/NF)                          | < = 1.0%  |

## General Product Overview

This is an ultra-high purity, reagent grade product, purified under cGMP conditions. 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 meets multicompendial specifications.

## Industry Application

Suitable for use in biological and biotech chemical process applications from R&D through scale cGMP production.

## Key Product Features

- Appears as a white to almost white crystalline powder
- Manufactured in accordance with IPEC
- 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; alpha-D-Galactose

## 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

1kg, 5kg, 10kg, 25kg, 50kg

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

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