

**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-3350****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 (EP/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                 |
| Proteins (EP)                              | Staphylococcus aureus (NF) Absent/g                |
|  | Lactose and 1,6-galactosyl-galactose (NF) < = 0.6% |
|  | Galacturonic acid (NF) < = 0.6%                    |
|  | Dextrose (NF) < = 0.6%                             |
|  | Tagatose (NF) < = 0.6%                             |
| Related Substances                         | 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-3350 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
- It 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.](#)

*This is not considered a controlled document. We are not responsible for any errors or omissions, and the user is responsible for any decisions based on the information herein.*