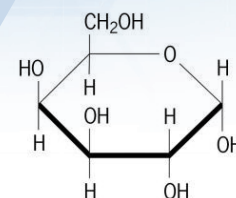


### D-GALACTOSE, LBLE-LEI, EP, BP, NF, GMP, Plant Derived

Low Bioburden, Low Endotoxin, Low Elemental Impurities, EP, BP, NF, GMP Manufactured, Excipient Grade Product

#### INTENDED FOR USE IN PHARMA MFG. REQUIRING ICH-Q7, EXCIPIENT GRADE QUALITY & REGULATORY COMPLIANCE

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 in regard to growth, BioSpectra's D-Galactose is manufactured to meet high purity specifications and low bioburden and endotoxin demands.



CAS #: 59-23-4

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

Solubility in Water (g/L): 600

F.W.: 180.16 g/mol

pKa @ 25°C: 12.4

### BIO EXCIPIENT GRADE | Product Code: GALP-3251 | Previously: GA3251

C<sub>6</sub>H<sub>12</sub>O<sub>6</sub> • F.W. 180.16 g/mol • CAS# 59-23-4



### NF Compendia

ANALYSIS		SPECIFICATIONS
<sup>2</sup> Acidity		Passes Test
<sup>2</sup> Appearance of Solution		Passes Test
<sup>1</sup> Assay (HPLC)		98.0% - 102.0%
<sup>2</sup> Identification A		Conforms to Reference
<sup>1</sup> Identification B		Passes Test
<sup>2</sup> Identification C		Passes Test
<sup>2</sup> Microbial Content	<i>Escherichia coli</i>	Absent
	<i>Pseudomonas aeruginosa</i>	Absent
	<i>Salmonella species</i>	Absent
	<i>Staphylococcus aureus</i>	Absent
	TAMC	<sup>3</sup> ≤ 50 CFU/g
	TYMC	≤ 50 CFU/g
<sup>1</sup> Related Substances	Glucose (HPLC) <sup>4</sup>	≤ 0.1%
	Lactose and 1,6-galactosyl-galactose	≤ 0.3%
	Galacturonic acid	≤ 0.2%
	Dextrose	≤ 0.6%
	Tagatose	≤ 0.2%
	Dulcitol	≤ 0.2%
	Arabinose	≤ 0.3%
	Any Unspecified Impurity	≤ 0.2%
Total Impurities	≤ 0.8%	
Residue on Ignition		≤ 0.5%
Optical Rotation, Specific Rotation @ 20°C		+78.0° to +81.5°
<sup>2</sup> Water		≤ 1.0%



<sup>1</sup>Alternate Validated Method

<sup>2</sup>Analyses are Harmonized

<sup>3</sup>Specification is more stringent than Compendia Monograph

\* = Low Bioburden, Low Endotoxin product

\*\* = Low Elemental Impurities product

Made in the USA

## EP Compendia

ANALYSIS		SPECIFICATIONS
<sup>2</sup> Acidity or Alkalinity		Passes Test
Appearance		White to almost white, crystalline or finely granulated powder
<sup>2</sup> Appearance of Solution		Passes Test
<sup>1</sup> Assay (HPLC)		<sup>3</sup> 98.0% - 102.0%
<sup>2</sup> Identification A		Conforms to Reference
<sup>1</sup> Identification B		Passes Test
<sup>2</sup> Identification C		Passes Test
<sup>2</sup> Microbial Content	TAMC	≤ 50 CFU/g
Proteins		≤ 0.1 mg/mL
<sup>1</sup> Related Substances	Sum of Impurities A and B	≤ 1.0%
	Unspecified Impurities: for each impurity	≤ 0.2%
	Total Impurities	≤ 0.8%
Sulfated Ash		≤ 0.1%
<sup>2</sup> Water		≤ 1.0%

<sup>1</sup>Alternate Validated Method <sup>2</sup>Analyses are Harmonized

<sup>3</sup>Specification is more stringent than Compendia Monograph

## Additional Analyses

ANALYSIS		SPECIFICATIONS
Endotoxins		≤ 1.0 EU/g
Trace Metals (USP <232> <233>)	Aluminum (Al)	≤ 63 ppb
	Arsenic (As) (inorganic)	≤ 50 ppb
	Barium (Ba) (NF) <sup>4</sup>	≤ 63 ppb
	Cadmium (Cd)	≤ 10 ppb
	Cobalt (Co)	≤ 50 ppb
	Chromium (Cr)	≤ 50 ppb
	Copper (Cu)	≤ 25 ppb
	Iron (Fe)	≤ 200 ppb
	Lead (Pb) (NF) <sup>4</sup>	≤ 50 ppb
	Manganese (Mn)	≤ 25 ppb
	Mercury (Hg) (inorganic)	≤ 50 ppb
	Molybdenum (Mo)	≤ 50 ppb
	Nickel (Ni)	≤ 50 ppb
	Selenium (Se)	≤ 50 ppb
	Tungsten (W)	≤ 50 ppb
	Vanadium (V)	≤ 200 ppb
	Zinc (Zn)	≤ 200 ppb
<sup>1</sup> Residual Ethanol		≤ 200 ppm <sup>3</sup>
<sup>1</sup> Residual Isopropanol		≤ 500 ppm <sup>3</sup>
<sup>1</sup> Residual Methanol		≤ 100 ppm <sup>3</sup>
<sup>1</sup> Residual Methyl Isobutyl Ketone		≤ 500 ppm

<sup>1</sup>Alternate Validated Method

<sup>2</sup>Analyses are Harmonized

<sup>3</sup>Specification is more stringent than Compendia Monograph <sup>4</sup>NF Compendial Method

## General Product Description:

- The Manufacturing of D-Galactose, Plant Derived GALP-3251 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment.
- D-Galactose, Plant Derived is a white to almost white crystalline powder
- Molecular Formula: C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>
- Molecular Weight: 180.16 g/mol
- CAS Number: 59-23-4
- BioSpectra certifies that all D-Galactose, Plant Derived GALP-3251 manufactured at BioSpectra and its raw materials are allergen free.
- BioSpectra certifies that all D-Galactose, Plant Derived GALP-3251 manufactured at BioSpectra, and its raw materials, are not derived from or come in contact with animal parts, products, and/or byproducts.
- D-Galactose, Plant Derived manufactured at BioSpectra and any raw materials used in the manufacture of D-Galactose, Plant Derived at BioSpectra are not subject to genetic modification.
- Synonyms: D-Galactopyranose

## GMP Compliance:

Bio Excipient Grade D-Galactose, Plant Derived GALP-3251 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of D-Galactose, Plant Derived is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

## Retest Date:

The recommended retest period for D-Galactose, Plant Derived is two years from the date of manufacture.

## Storage and Shipping Conditions:

Keep container tightly closed and store in a clean, dry and well-ventilated area. Store in the original container.

## Package Sizes:

10kg & 25kg pails and 50kg drum.