BIOSPECTRA
Premium Pharmaceutical Ingredients

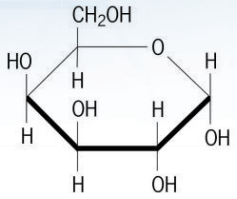
Excipient
ICH-Q7 GMP Manufactured Product

D-GALACTOSE, LBLE, EP, NF, GMP, Plant Derived

Low Bioburden, Low Endotoxin, EP, 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: $C_6H_{12}O_6$
Solubility in Water (g/L): 600
F.W.: 180.16 g/mol
pKa @ 25˚C: 12.4

BIO EXCIPIENT GRADE | Product Code: GALP-3250 | Previously: GA3250

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

Made in the USA

EP Compendia

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity		Passes Test
Appearance		White to almost white, crystalline powder
Appearance of Solution		Passes Test
Assay		97.0% – 102.0%
Barium		Passes Test
Identification A		Passes Test
Identification B		Passes Test
Identification C		Passes Test
Microbial Content	TAMC	≤ 100 CFU/g
Proteins		≤ 0.1 mg/ml
Related Substances	Impurities A and B Unspecified Impurities Total Impurities	≤ 1.0% ≤ 0.3% each ≤ 2.0%
Sulfated Ash		≤ 0.1%
Water		≤ 1.0%

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Made in the USA

NF Compendia

ANALYSIS		SPECIFICATIONS
Acidity		Passes Test
Appearance of Solution		Passes Test
Assay		98.0% - 102.0%
Barium		Passes Test
Identification A		Passes Test
Identification B		Passes Test
Identification C		Passes Test
Limit of Lead		≤ 0.5 ppm
Microbial Content	*Escherichia coli*	Absent
	Pseudomonas aeruginosa	Absent
	Salmonella species	Absent
	Staphylococcus aureus	Absent
	TAMC	≤ 1000 CFU/g
	TYMC	≤ 100 CFU/g
[1]Related Substances	Lactose and 1, 6-galactosyl-galactose	≤ 0.6%
	Galacturonic acid	≤ 0.6%
	Dextrose	≤ 0.6%
	Tagatose	≤ 0.6%
	Dulcitol	≤ 0.6%
	Arabinose	≤ 0.6%
	Any Unspecified Impurity	≤ 0.2%
	Total Impurities	≤ 1.0%
Residue on Ignition		≤ 0.1%
Optical Rotation, Specific Rotation		+78.0° to +81.5°
Water		≤ 1.0%

Additional Analyses

ANALYSIS	SPECIFICATIONS
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:

- The Manufacturing of D-Galactose, Plant Derived GALP-3250 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: $C_6H_{12}O_6$
- Molecular Weight: 180.16 g/mol
- CAS Number: 59-23-4
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all D-Galactose, Plant Derived GALP-3250 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-3250 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:

Ship and store in ambient temperature. Keep container tightly closed in a dry and well-ventilated place.

Package Sizes:

10kg & 25kg pails.

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