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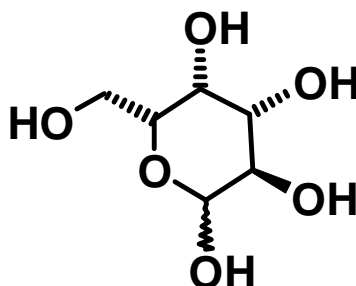
Product Specifications

D-(+)-Galactose (animal-origin free, vegetal-derived)

CAS 59-23-4

Grade: cGMP; NF/EP

Structure:



Mol. Formula
Source

$C_6H_{12}O_6$
Vegetal-derived (Peach Gum Tree Resin)

Mol. Wt.

180.18

Test

Specification

National Formulary (NF)

Identity A	Conforms
Identity B	Conforms
Appearance	White microcryst. powder
Appearance of Solution	Clear and less than B ₈
Sp. Rot., $[\alpha]_D$	+78.0° to +81.5°
Water	≤ 1.0%
Ash (residue on ignition)	≤ 0.1%
Acidity	Conforms
Barium	Conforms
Limit of Lead	≤ 0.5 ppm

- cont'd -

- cont'd -

<i>Test</i>	<i>Specification</i>	<i>Results</i>
<u>Microbiological Specification</u>		
Total plate count	≤ 100 CFU/g	
Molds and Yeasts	≤ 100 CFU/g	
Salmonella	Absence	
E. Coli	Absence	
Staphylococcus Aureus	Absence	
Pseudomonas Aeruginosa	Absence	
Endotoxin	≤ 10 EU/g	
European Pharmacopeia (EP)		
Identity A	Conforms	
Identity B	Conforms	
Identity C	Conforms	
Appearance	White microcryst. powder	
Appearance of Solution	Clear and less than B ₈	
Protein (UV)	≤ 0.1 mg/mL	
Assay (hplc)	97.0-102.0%	
Impurities		
Impurities A & B	≤ 1.0%	
Unspecified Impurities	≤ 0.3%	
Total Impurities	≤ 2.0%	
Water	≤ 1%	
Sulfated Ash	≤ 0.1%	
Acidity	Conforms	
Barium	Conforms	
<u>Microbiological Specification</u>		
Total plate count	< 100 CFU/g	
Residual Solvents		
EtOH	500 ppm	
MeOH	100 ppm	
MIBK	500 ppm	

Storage: Maintain in cool, dry containment.

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Non-GMO: This product is derived from a non-GMO vegetal source as designated under EP regulations 1829/2003 and 1830/2003.

TSE/BSE: During production, storage and transport, all contact with any material of animal origin was excluded. Therefore, the requirements set forth in of the EP Comm. Directive 1999/82/EEC, CPMP/BWP/1230/98, and EP 01/2008: 50208 do not apply.