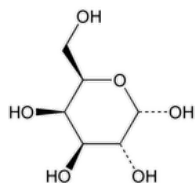


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Galactose



$C_6H_{12}O_6$ 180.16

D-Galactopyranose CAS RN®: 59-23-4.

DEFINITION

Change to read:

▲Galactose contains NLT 98.0% and NMT 102.0% of D-galactopyranose ($C_6H_{12}O_6$), calculated on the anhydrous basis. It is obtained either as one of the products of the metabolism of lactose, a naturally occurring sugar in dairy products, by the digestive enzyme lactase, or from arabinogalactans isolated from a plant-derived source.▲ (NF 1-Aug-2020)

IDENTIFICATION

Change to read:

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)

▲[NOTE—Disregard any peaks at about 875 and 889 cm^{-1} .]▲ (NF 1-Aug-2020)

Delete the following:

▲ • B. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).

Solution A: Methanol and water (60:40)

Standard solution A: 500 µg/mL of [USP Galactose RS](#) in *Solution A*

Standard solution B: 500 µg/mL each of [USP Galactose RS](#), [USP Dextrose RS](#), and USP Lactose Monohydrate RS in *Solution A*

Sample solution: Dissolve 10 mg of Galactose in 20 mL of *Solution A*.

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Application volume: 2 µL

Developing solvent system: Propanol and water (85:15)

Spray reagent: 0.5 g of thymol in a mixture of alcohol and sulfuric acid (95:5)

System suitability

Sample: *Standard solution B*

Suitability requirements

Resolution: There must be three clearly resolved spots in the chromatogram for *Standard solution B*.

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Develop the plate in an unsaturated tank. After the solvent front has moved over 15 cm, remove the plate from the tank. Dry the plate with warm air, then spray the plate with *Spray reagent*. Heat for 10 min in an oven at 130°.

Acceptance criteria: The R_f of the principal spot of the *Sample solution* corresponds to that of *Standard solution A*. ▲ (NF 1-Aug-2020)

Add the following:

▲ • B. **Chromatographic Identity**

Analysis: Proceed as directed in the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to the galactose peak of the *Standard solution*, as obtained in the Assay. ▲ (NF 1-Aug-2020)

Add the following:

▲ • C.

Sample solution: 10 mg/mL

Analysis: To 10 mL of the *Sample solution* add 3 mL of [alkaline cupric tartrate TS](#) and heat.

Acceptance criteria: An orange or red precipitate is formed. ▲ (NF 1-Aug-2020)

ASSAY

Add the following:

▲ • Procedure

Mobile phase: 0.009 N [sulfuric acid](#)

System suitability solution: 10 mg/mL of [USP Galactose RS](#) and 0.2 mg/mL each of [USP Arabinose RS](#), galacturonic acid, ¹[USP Dextrose RS](#), and [USP Anhydrous Lactose RS](#) in *Mobile phase*

[NOTE—Use plastic HPLC vials for the *Standard solution* and *Sample solution*.]

Standard solution: 10 mg/mL of [USP Galactose RS](#) in *Mobile phase*

Sample solution: 10 mg/mL of Galactose in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: Two 7.8-mm × 30-cm columns in tandem; 9-μm packing [L17](#)

Temperatures

Column: 35°

Detector: 40°

Flow rate: 0.25 mL/min

Injection volume: 25 μL

Run time: 70 min

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for lactose, galacturonic acid, dextrose, galactose, and arabinose are listed in [Table 1](#).]

Suitability requirements

Resolution: NLT 3.0 between the lactose and galacturonic acid peaks; NLT 1.5 between the galacturonic acid and dextrose peaks; NLT 2.0 between the dextrose and galactose peaks; NLT 3.0 between the galactose and arabinose peaks, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of galactose in the portion of Galactose taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of galactose from the *Sample solution*

r_S = peak area of galactose from the *Standard solution*

C_S = concentration of USP Galactose RS in the *Standard solution* (mg/mL)

C_U = concentration of Galactose in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis ▲ (NF 1-Aug-2020)

IMPURITIES

Add the following:

▲ • Related Substances

Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.