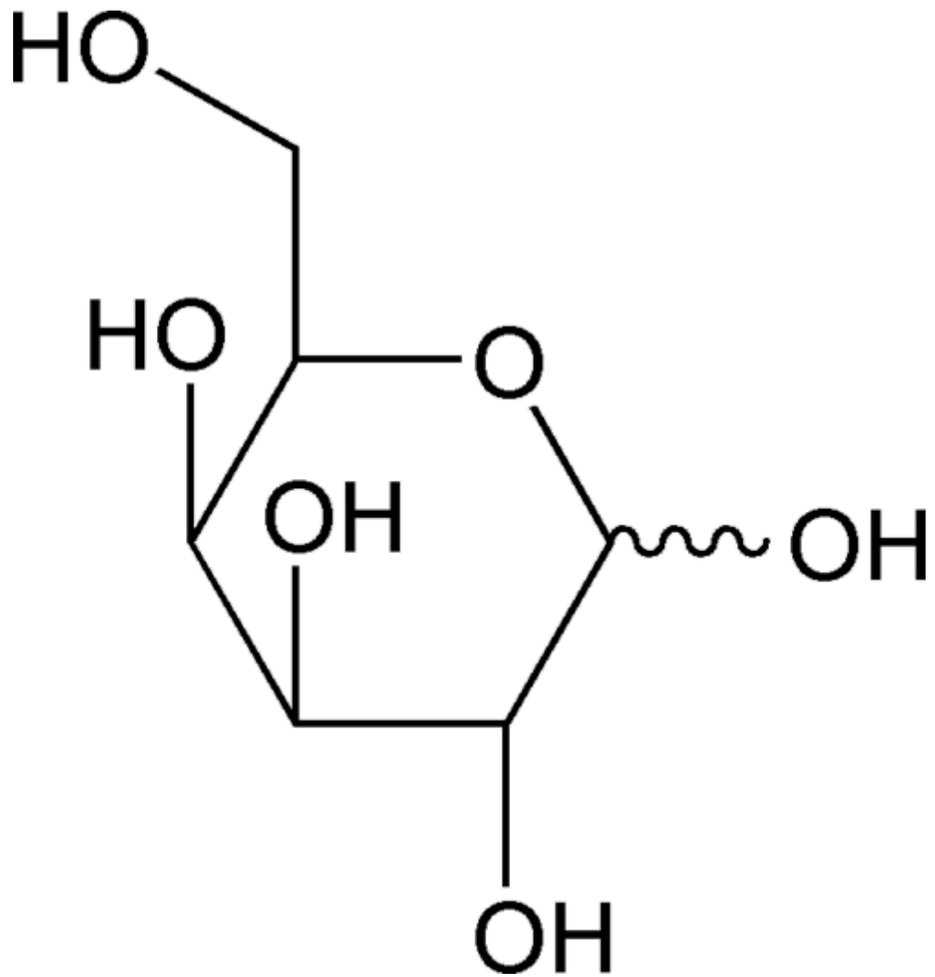
Galactose



$C_6H_{12}O_6$ 180.16

α-D-Galactopyranose [*3646-73-9*].

» Galactose is one of the products of the metabolism of lactose, a naturally occurring sugar in dairy products, by the digestive enzyme lactase.

Add the following:

▲**Packaging and storage—** Preserve in a tight container. No storage requirements specified.▲*NF24*

USP Reference standards ⟨ 11 ⟩ **—** *USP Dextrose RS*. *USP Galactose RS*. *USP Lactose Monohydrate RS*.

Appearance of solution— Dissolve, with heating at 50°, 10.0 g of Galactose in 50 mL of carbon dioxide-free water. The solution is not more intensely colored than a solution prepared immediately before use by mixing 3.0 mL of ferric chloride CS, 3.0 mL of cobaltous chloride CS, and 2.4 mL of cupric sulfate CS with dilute hydrochloric acid (10 g per L) to make 10 mL, and diluting 1.5 mL of this solution with the dilute hydrochloric acid to 100 mL. Make the comparison by viewing the substance and the solution downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* ⟨ 631 ⟩).

Identification—

A: *Infrared Absorption* ⟨ 197K ⟩ .

B: *Thin-Layer Chromatographic Identification Test* ⟨ 201 ⟩ —

Test solution— Dissolve 10 mg in 20 mL of a mixture of methanol and water (3:2).

Standard solution 1: 500 µg per mL in a mixture of methanol and water (3:2).

Standard solution 2— Prepare a solution using *USP Galactose RS*, *USP Dextrose RS*, and *USP Lactose Monohydrate RS*, each at a concentration of 500 µg per mL in a mixture of methanol and water (3:2).

Application volume: 2 µL.

Developing solvent system: propanol and water (85:15).

Procedure— 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 a thymol solution (0.5 g in a mixture of alcohol and sulfuric acid [95:5]). Heat for 10 minutes in an oven at 130°. The R_F of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution.* [NOTE—There must be three clearly resolved spots in the chromatogram for *Standard solution 2* in order for the results to be valid.]

Specific rotation ⟨ 781S ⟩ **:** between +78.0° and +81.5° at 20°.

Test solution: Transfer 10.0 g to a 100-mL volumetric flask, and dissolve in 80 mL of water. Add 0.2 mL of ammonia TS, allow to stand for 30 minutes, then dilute with water to volume.

Microbial limits ⟨ 61 ⟩ **—** It meets the requirements of the test for absence of *Salmonella* species, *Escherichia coli, Staphylcoccus aureus,* and *Pseudomonas aeruginosa.* The total aerobic microbial count does not exceed 1000 cfu per g, and the total combined molds and yeasts count does not exceed 100 cfu per g.

Acidity— Dissolve 10.0 g, with heating at 50°, in 40 mL of carbon dioxide-free water. Dilute with carbon dioxide-free water to 50 mL [NOTE—Use this solution for the *Barium* test]. To 30 mL of this solution, add 0.3 mL of phenolphthalein TS, and titrate with 0.01 N sodium hydroxide to a pink color: not more than 1.5 mL of 0.01 N sodium hydroxide is required to produce a pink color.

Water, *Method I* ⟨ 921 ⟩ **:** not more than 1.0%.

Residue on ignition ⟨ 281 ⟩ **:** not more than 0.1%.

Barium—

Standard solution— Add 6 mL of water to 5 mL of the solution prepared for the *Acidity* test.

Test solution— Add 5 mL of water and 1 mL of dilute sulfuric acid to 5 mL of the solution prepared for the *Acidity* test. Allow to stand for 1 hour: any opalescence in the *Test solution* is not more intense than that of the *Standard solution.*

Limit of lead—

Diluent— Dilute 12 mL of acetic acid with water to 100 mL. Mix equal parts of this solution and water to prepare the *Diluent.*

Lead standard stock solution— Transfer an accurately weighed quantity of lead nitrate, about 400 mg, to a 250-mL volumetric flask, dilute with water to volume, and mix.

Lead standard solution— Dilute 1.0 mL of *Lead standard stock solution* with water to 10 mL. Dilute 1.0 mL of this solution with water to 10 mL.

Standard solutions— To three identical flasks, add 0.5 mL, 1.0 mL, and 1.5 mL of *Lead standard solution,* respectively, and then add to each flask 20.0 g of galactose. Dilute with *Diluent* to 100 mL. To each flask add 2.0 mL of ammonium pyrrolidinedithiocarbamate solution (10 g per L) and 10.0 mL of methyl isobutyl ketone, then shake for 30 seconds. [NOTE—Protect from light.] Allow the layers to separate, and use the methyl isobutyl ketone (upper) layer for analysis.

Test solution— Dissolve 20.0 g of Galactose in *Diluent,* and dilute with *Diluent* to 100 mL. Add 2.0 mL of ammonium pyrrolidinedithiocarbamate solution (10 g per L) and 10.0 mL of methyl isobutyl ketone, and shake for 30 seconds. [NOTE—Protect from light.] Allow the layers to separate, and use the methyl isobutyl ketone (upper) layer for analysis.

Procedure— Concomitantly determine, at least in triplicate, the absorbances of the *Standard solutions* and the *Test solution* at 283.3 nm with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* ⟨ 851 ⟩) equipped with a lead hollow-cathode lamp as the radiation source and an air–acetylene flame. Record the average steady readings for each of the *Standard solutions* and the *Test solution.* Plot the absorbances of the *Standard solutions* and the *Test solution* versus the amount of lead added. Extrapolate the line joining the points on the graph until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of lead in the *Test solution:* not more than 0.5 µg per g is found.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

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USP29–NF24 Page 3336
Pharmacopeial Forum : Volume No. 31(1) Page 88
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