Glucose Hydrate

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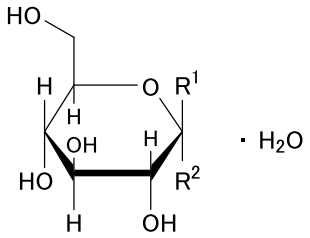

α-D-glucopyranose monohydrate: R^1=H, R^2=OH
β-D-glucopyranose monohydrate: R^1=OH, R^2=H

$C_6H_{12}O_6.H_2O$: 198.17
D-Glucopyranose monohydrate
[*77938-63-7*]

This monograph is harmonized with the European Pharmacopoeia and the U.S. Pharmacopeia. The parts of the text that are not harmonized are marked with symbols (◆ ◆) or (◇ ◇).

Glucose Hydrate is the monohydrate of D-glucopyranose derived from starch.

It contains not less than 97.5% and not more than 102.0% of glucose [D-glucopyranose ($C_6H_{12}O_6$: 180.16)], calculated on the anhydrous basis.

◆**Description** Glucose Hydrate occurs as white crystals or crystalline powder, and has a sweet taste.

It is freely soluble in water, sparingly soluble in methanol, and slightly soluble in ethanol (95).◆

Identification ◇**(1)** Add 2 to 3 drops of a solution of Glucose Hydrate (1 in 20) to 5 mL of boiling Fehling's TS: a red precipitate is produced.◇

(2) Perform the test with 20 μL each of the sample solution and standard solution obtained in the Assay as directed under Liquid Chromatography *<2.01>* according to the following conditions: the principal peak in the chromatogram obtained from the sample solution is similar in retention time and size to the principal peak in the chromatogram obtained from the standard solution.

Operating conditions —

Proceed as directed in the operating conditions in the Assay.

System suitability —

Proceed as directed in the system suitability in the Assay.

Purity **(1)** Clarity and color of solution—Dissolve 10.0 g of Glucose Hydrate in 15 mL of water: the solution is clear, and its clarity is the same as that of water or its opalescence is not more pronounced than that of reference suspension I, and it is not more intensely colored than the following control solution.

Control solution: To a mixture of 2.5 mL of Cobalt (II) Chloride CS, 6.0 mL of Iron (III) Chloride CS, and 1.0 mL of Copper (II) Sulfate CS, add diluted dilute hydrochloride (1 in 10) to make 1000 mL.

◆**(2)** Heavy metals *<1.07>*—Proceed with 5.0 g of Glucose Hydrate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 4 ppm).◆

(3) Related substances—Use the sample solution obtained in the Assay as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 250 mL, and use this solution as the standard solution (1). Pipet 25 mL of the standard solution (1), add water to make exactly 200 mL, and use this solution as the standard solution (2). Perform the test with exactly 20 μL each of the sample solution, the standard solution (1) and the standard solution (2) as directed under Liquid Chromatography *<2.01>* according to the following conditions. Determine each peak area by the automatic integration method: the total area of maltose and isomaltose, having the relative retention time of about 0.8 to glucose, obtained from the sample solution, is not larger than the peak area of glucose obtained from the standard solution (1) (not more than 0.4%), and the area of maltotriose, having the relative retention time of about 0.7 to glucose, obtained from the sample solution, is not larger than 1/2 times the peak area of glucose obtained from the standard solution (1) (not more than 0.2%), and the area of fructose, having the relative retention time of about 1.3 to glucose, obtained from the sample solution, is not larger than 3 times the peak area of glucose obtained from the standard solution (2) (not more than 0.15%), and the area of the peak other than glucose and the peaks mentioned above, obtained from the sample solution, is not larger than 2 times the peak area of glucose obtained from the standard solution (2) (not more than 0.10%). Furthermore, the total area of the peaks other than glucose, obtained from the sample solution, is not larger than 1.25 times the peak area of glucose obtained from the standard solution (1) (not more than 0.5%). For these calculations the peak areas not larger than the peak area of glucose obtained from the standard solution (2) are excluded (disregard limit: 0.05%).

Operating conditions —

Detector, column, column temperature, mobile phase and flow rate: Proceed as directed in the operating conditions in the Assay.

Time span of measurement: About 1.5 times as long as the retention time of glucose.

System suitability —

System performance: Proceed as directed in the system suitability in the Assay.

◇Test for required detectability: Confirm that the peak area of glucose obtained with 20 μL of the standard solution (2) is equivalent to 8.75 to 16.25% of that obtained with 20 μL of the standard solution (1).

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution (1) under the above operating conditions, the relative standard deviation of the peak area of glucose is not more than 1.0%.◇

(4) Dextrin－To 1.0 g of powdered Glucose Hydrate add 20 mL of ethanol (95), and boil under a reflux condenser: the solution is clear.

(5) Soluble starch and sulfite－To 7.4 g of Glucose Hydrate add 15 mL of water, heat on a water bath, cool, and add 25 μL of 0.05 mol/L iodine TS: a yellow color develops (not more than 15 ppm as SO_3).

Conductivity <*2.51*> Dissolve 20.0 g of Glucose Hydrate in a fleshly boiled and cooled distilled water to make 100 mL, and use this solution as the sample solution. Measure the conductivity of the sample solution at 25±0.1℃ while gently stirring with a magnetic stirrer: not more than 20 $\mu S \cdot cm^{-1}$.

Water <*2.48*> 7.5 – 9.5% (0.25 g, volumetric titration, direct titration).

Assay Weigh accurately about 0.33 g of Glucose Hydrate and 0.3 g of ◆Glucose RS◆ (separately determine the water <*2.48*> in the same manner as Purified Glucose), dissolve separately in water to make exactly 10 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography <*2.01*> according to the following conditions, and determine the peak areas, A_T and A_S, of glucose in each solution.

$$\text{Amount (g) of glucose } (C_6H_{12}O_6) = M_S \times A_T / A_S$$

M_S: Amount (g) of Glucose RS taken, calculated on the anhydrous basis

Operating conditions－

Detector: A differential refractometer maintained at a constant temperature (40℃ for example).

Column: A stainless steel column 7.8 mm in inside diameter and 30 cm in length, packed with strongly acidic ion-exchange resin for liquid chromatography (Ca type) composed with a sulfonated polystyrene cross-linked with 8% of divinylbenzene (9 μm in particle diameter).

Column temperature: 85±1℃.

Mobile phase: Water.

Flow rate: 0.3 mL/min (the retention time of glucose is about 21 minutes).

System suitability－

System performance: Dissolve 5 mg of maltose, 5 mg of maltotriose and 5 mg of fructose in 50 mL of water, and use this solution as the solution for system suitability test. When the procedure is run with 20 μL each of the solution for system suitability test and the standard solution (2) in Purity (3) under the above operating conditions, maltotriose, maltose, isomaltose, glucose and fructose are eluted in this order, the relative retention times of maltotriose, maltose, isomaltose and fructose to glucose are about 0.7, about 0.8, about 0.8 and about 1.3, respectively, and the resolution between the peaks of maltotriose and maltose is not less than 1.3.

◇System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of glucose is not more than 1.0%.◇

◆**Containers and storage** Containers－Tight containers.◆

Add the following to 9.01 Reference Standards (1):

Glucose RS