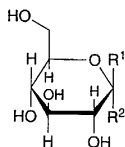


Glucose

ブドウ糖



α -D-Glucopyranose: R¹=H, R²=OH
 β -D-Glucopyranose: R¹=OH, R²=H

C₆H₁₂O₆: 180.16
 D-Glucopyranose [50-99-7]

Glucose is α -D-glucopyranose, β -D-glucopyranose, or a mixture of them, and when dried, it contains not less than 99.5% of C₆H₁₂O₆.

Description Glucose occurs as white crystals or crystalline powder. It is odorless, and has a sweet taste.

It is freely soluble in water, slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

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

Purity (1) Clarity and color of solution—Add 25 g of Glucose to 30 mL of water in a Nessler tube, warm at 60°C in a water bath until solution is effected, cool, and add water to make 50 mL: the solution is clear and has no more color than the following control solution.

Control solution: To a mixture of 1.0 mL of Cobaltous Chloride Stock CS, 3.0 mL of Ferric Chloride stock CS, and 2.0 mL of Cupric Sulfate Stock CS, add water to make 10.0 mL. To 3.0 mL of this solution add water to make 50 mL.

(2) Acid—Dissolve 5.0 g of Glucose in 50 mL of freshly boiled and cooled water, and add 3 drops of phenolphthalein TS and 0.60 mL of 0.01 mol/L sodium hydroxide VS: a red color develops.

(3) Chloride—Perform the test with 2.0 g of Glucose. Prepare the control solution with 1.0 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.018%).

(4) Sulfate—Perform the test with 2.0 g of Glucose. Prepare the control solution with 1.0 mL of 0.005 mol/L sulfuric acid VS (not more than 0.024%).

(5) Heavy metals—Proceed with 5.0 g of Glucose 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).

(6) Arsenic—Dissolve 1.5 g of Glucose in 5 mL of water, add 5 mL of dilute sulfuric acid and 1 mL of bromine TS, heat on a water bath for 5 minutes, and concentrate to 5 mL. After cooling, perform the test with this solution as the test solution using Apparatus B (not more than 1.3 ppm).

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

(8) Soluble starch and sulfite—Dissolve 1.0 g of Glucose in 10 mL of water, and add 1 drop of iodine TS: a yellow color develops.

Loss on drying Not more than 1.0% (1 g, 105°C, 6 hours).

Residue on ignition Not more than 0.10% (2 g).

Assay Weigh accurately about 10 g of Glucose, previously dried, dissolve in 0.2 mL of ammonia TS and water to make exactly 100 mL, allow to stand for 30 minutes, and determine the optical rotation, α_D , of this solution at 20 ± 1°C in a 100-mm cell as directed under the Optical Rotation Determination.

Amount (mg) of C₆H₁₂O₆ = $\alpha_D \times 1895.4$

Containers and storage Containers—Tight containers.

Glucose Injection

ブドウ糖注射液

Glucose Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of glucose (C₆H₁₂O₆: 180.16).

Method of preparation Prepare as directed under Injections, with Glucose. No preservative is added.

Description Glucose Injection is a clear, colorless liquid. It has a sweet taste. It occurs as a colorless to pale yellow, clear liquid when its labeled concentration exceeds 40%.

Identification Measure a volume of Glucose Injection, equivalent to 0.1 g of Glucose according to the labeled amount, and, if necessary, add water or evaporate on a water bath to a volume of 2 mL. Add 2 to 3 drops of the solution to 5 mL of boiling Fehling's TS: a red precipitate is produced.

pH 3.5 – 6.5 In the case where the labeled concentration of the injection exceeds 5%, dilute to 5% with water before the test.

Purity 5-Hydroxymethylfurfural and related substances—Measure exactly a volume of Glucose Injection, equivalent to 2.5 g of Glucose according to the labeled amount, and add water to make exactly 100 mL. Determine the absorbance of this solution at 284 nm as directed under the Ultraviolet-visible Spectrophotometry: it is not more than 0.80.

Bacterial endotoxins Less than 0.50 EU/mL.

Assay Measure accurately a volume of Glucose Injection, equivalent to about 4 g of glucose (C₆H₁₂O₆), and add 0.2 mL of ammonia TS and water to make exactly 100 mL. Shake the solution well, allow to stand for 30 minutes, and determine the optical rotation, α_D , at 20 ± 1°C in a 100-mm cell as directed under the Optical Rotation Determination.

Amount (mg) of glucose (C₆H₁₂O₆) = $\alpha_D \times 1895.4$

Containers and storage Containers—Hermetic containers. Plastic containers for aqueous injections may be used.