Assay Weigh accurately about 0.6 g of Magnesium Sulfate, previously ignited at 450°C for 3 hours after drying at 105°C for 2 hours, and dissolve in 2 mL of dilute hydrochloric acid and water to make exactly 100 mL. Pipet 25 mL of this solution, add 50 mL of water and 5 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and titrate with 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS (indicator: 0.04 g of eriochrome black T-sodium chloride indicator). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 6.018 mg of $MgSO_4$

Containers and storage Containers—Well-closed containers.

Magnesium Sulfate Injection

硫酸マグネシウム注射液

Magnesium Sulfate Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of magnesium sulfate ($MgSO_4.7H_2O$: 246.47).

Method of preparation Prepare as directed under Injections, with Magnesium Sulfate.

Description Magnesium Sulfate Injection is a clear, colorless liquid.

It is neutral.

Identification Measure a volume of Magnesium Sulfate Injection, equivalent to 0.5 g of Magnesium Sulfate according to the labeled amount, and add water to make 20 mL: the solution responds to the Qualitative Tests for magnesium salt and for sulfate.

Bacterial endotoxins Perform the test with Magnesium Sulfate Injection after diluting with water for bacterial endotoxins test to 5 w/v%: less than 0.09 EU/mg.

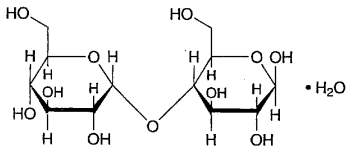
Assay Measure exactly a volume of Magnesium Sulfate Injection, equivalent to about 0.3 g of magnesium sulfate ($MgSO_4.7H_2O$), and add water to make 75 mL. Then add 5 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and proceed as directed in the Assay under Magnesium Sulfate.

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 12.324 mg of $MgSO_4.7H_2O$

Containers and storage Containers—Hermetic containers.

Maltose

マルトース



$C_{12}H_{22}O_{11}.H_2O$: 360.31

4-*O*-α-D-Glucopyranosyl-β-D-glucopyranose monohydrate [*6363-53-7*]

Maltose, when dried, contains not less than 98.0% of $C_{12}H_{22}O_{11}.H_2O$.

Description Maltose occurs as white crystals or crystalline powder.

It has a sweet taste.

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

Identification **(1)** Dissolve 0.5 g of Maltose in 5 mL of water, add 5 mL of ammonia TS, and heat for 5 minutes on a water bath: an orange color develops.

(2) Add 2 to 3 drops of a solution of Maltose (1 in 50) to 5 mL of boiling Fehling TS: a red precipitate is formed.

Optical rotation $[\alpha]_D^{20}$: +126 – +131° Weigh accurately about 10 g of Maltose, previously dried, dissolve in 0.2 mL of ammonia TS and water to make exactly 100 mL, and determine the optical rotation of this solution in a 100-mm cell.

pH The pH of a solution of Maltose (1 in 10) is between 4.5 and 6.5.

Purity **(1)** Clarity and color of solution—Put 10 g of Maltose in 30 mL of water in a Nessler tube, warm at 60°C in a water bath to dissolve, and after cooling, add water to make 50 mL: the solution is clear, and has no more color than the following control solution.

Control solution: Add water 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 to make 10.0 mL. To 1.0 mL of this solution add water to make 50 mL.

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

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

(4) Heavy metals—Proceed with 5.0 g of Maltose according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 4 ppm).

(5) Arsenic—Dissolve 1.5 g of Maltose 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, then heat to concentrate to 5 mL, and use this solution as the test solution after cooling. Perform the test using Apparatus B (not more than 1.3 ppm).

(6) Dextrin, soluble starch and sulfite—Dissolve 1.0 g of Maltose in 10 mL of water, and add 1 drop of iodine TS: a yellow color appears, and the color changes to a blue by adding 1 drop of starch TS.

(7) Nitrogen—Weigh accurately about 2.0 g of Maltose, and perform the test as directed under the Nitrogen Determination using 10 mL of sulfuric acid for the decomposition and 45 mL of a solution of sodium hydroxide (2 in 5) for the addition: the amount of nitrogen (N: 14.01) is not more than 0.01%.

(8) Related substances—Dissolve 0.5 g of Maltose in 10 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following operating conditions. Determine the peak areas from both solutions by the automatic integration method: the total area of the peaks which appear before the peak of maltose from the sample solution is not larger than 1.5 times of the peak area of maltose from the standard solution, and the total area of the peaks which appear after the peak of maltose from the sample solution is not larger than 0.5 time of the peak area of maltose from the standard solution.

Operating conditions—

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

Detection sensitivity: Adjust the sensitivity so that the peak height of maltose obtained from 20 μL of the standard solution is about 30 mm.

Time span of measurement: About 2 times as long as the retention time of maltose.

Loss on drying Not more than 0.5% (1 g, 80°C, 4 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.1 g each of Maltose and Maltose Reference Standard, previously dried, dissolve in exactly 10 mL each of the internal standard solution, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following operating conditions, and determine the ratios, Q_T and Q_S, of the peak area of maltose to that of the internal standard.

$$\text{Amount (mg) of } C_{12}H_{22}O_{11}.H_2O = \text{amount (mg) of Maltose Reference Standard} \times \frac{Q_T}{Q_S}$$

Internal standard solution—A solution of ethylene glycol (1 in 50).

Operating conditions—

Detector: A differential refractometer.

Column: A stainless steel column about 8 mm in inside diameter and about 55 cm in length, packed with gel-type strong acid cation-exchange resin for liquid chromatography (degree of cross-linking: 8 %) (10 μm in particle diameter).

Column temperature: A constant temperature of about 50°C.

Mobile phase: Water

Flow rate: Adjust the flow rate so that the retention time of maltose is about 18 minutes.

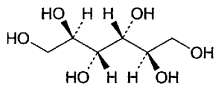
Selection of column: Dissolve 0.25 g of maltose, 0.25 g of glucose and 0.4 g of ethylene glycol in water to make 100 mL. Proceed with 20 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of maltose, glucose and ethylene glycol in this order with the resolution of between the peaks of maltose and glucose being not less than 4.

Containers and storage Containers—Tight containers.

D-Mannitol

D-Mannite

D-マンニトール



$C_6H_{14}O_6$: 182.17

D-Mannitol [*69-65-8*]

D-Mannitol, when dried, contains not less than 98.0% of $C_6H_{14}O_6$.

Description D-Mannitol occurs as white crystals or powder. It is odorless, and has a sweet taste with a cold sensation.

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

It dissolves in sodium hydroxide TS.

Identification (1) To 5 drops of a saturated solution of D-Mannitol add 1 mL of iron (III) chloride TS and 5 drops of a solution of sodium hydroxide (1 in 5): a yellow precipitate is produced. Shake this solution vigorously: a clear solution is produced. On addition of a solution of sodium hydroxide (1 in 5), no precipitate is produced.

(2) Determine the infrared absorption spectrum of D-Mannitol as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

Optical rotation $[\alpha]_D^{20}$: + 137 − + 145° Weigh accurately about 1.0 g of D-Mannitol, previously dried, dissolve in 80 mL of a solution of hexaammonium heptamolybdate tetrahydrate (1 in 20), and add diluted sulfuric acid (1 in 35) to make exactly 100 mL. Measure the optical rotation of this solution in a 100-mm cell.

Melting point 166 - 169°C

Purity (1) Clarity and color of solution—Dissolve 2.0 g of D-Mannitol in 10 mL of water by warming: the solution is clear and colorless.

(2) Acid—Dissolve 5.0 g of D-Mannitol in 50 mL of freshly boiled and cooled water, and add 1 drop of phenolphthalein TS and 0.50 mL of 0.01 mol/L sodium hydroxide VS: a red color develops.

(3) Chloride—Perform the test with 2.0 g of D-Mannitol. Prepare the control solution with 0.40 mL of 0.01