

**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<sub>4</sub>

**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<sub>4</sub>·7H<sub>2</sub>O: 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.

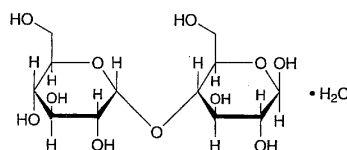
**Assay** Measure exactly a volume of Magnesium Sulfate Injection, equivalent to about 0.3 g of magnesium sulfate (MgSO<sub>4</sub>·7H<sub>2</sub>O), and add water to make 75 mL. Then add 5 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and proceed as directed in the Assay under Magnesium Sulfate.

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS  
= 12.324 mg of MgSO<sub>4</sub>·7H<sub>2</sub>O

**Containers and storage** Containers—Hermetic containers.

## Maltose

### マルトース



C<sub>12</sub>H<sub>22</sub>O<sub>11</sub>·H<sub>2</sub>O: 360.31  
4-O- $\alpha$ -D-Glucopyranosyl- $\beta$ -D-glucopyranose  
monohydrate [6363-53-7]

Maltose, when dried, contains not less than 98.0% of C<sub>12</sub>H<sub>22</sub>O<sub>11</sub>·H<sub>2</sub>O.

**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** [ $\alpha$ ]<sub>D</sub><sup>20</sup>: +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).