

(6) Arsenic—To 0.4 g of Magnesium Silicate add 5 mL of dilute hydrochloric acid, heat gently to boiling while shaking well, cool rapidly, and centrifuge. Mix the residue with 5 mL of dilute hydrochloric acid with shaking, centrifuge, then add 10 mL of water to the residue, and repeat the extraction in the same manner. Concentrate the combined extracts on a water bath to 5 mL. Use this solution as the test solution, and perform the test using Apparatus B (not more than 5 ppm).

Loss on ignition Not more than 34% (0.5 g, 850°C, 3 hours).

Acid-consuming capacity Place about 0.2 g of Magnesium Silicate, accurately weighed, in a glass-stoppered flask, add exactly 30 mL of 0.1 mol/L hydrochloric acid VS and 20 mL of water, shake at $37 \pm 2^\circ\text{C}$ for 1 hour, and cool. Pipet 25 mL of the supernatant liquid, and titrate the excess hydrochloric acid, while stirring well, with 0.1 mol/L sodium hydroxide VS until the pH becomes 3.5.

1 g of Magnesium Silicate, calculated on the anhydrous basis by making allowance for the observed loss on ignition determined as directed in the preceding Loss on ignition, consumes not less than 140 mL and not more than 160 mL of 0.1 mol/L hydrochloric acid VS.

Assay (1) Silicon dioxide—Weigh accurately about 0.7 g of Magnesium Silicate, add 10 mL of 0.5 mol/L sulfuric acid TS, evaporate on a water bath to dryness, add 25 mL of water to the residue, and heat on a water bath for 15 minutes with occasional stirring. Filter the supernatant liquid through filter paper for assay, add 25 mL of hot water to the residue, stir, and decant the supernatant liquid on the filter paper to filter. Wash the residue in the same manner with two 25-mL portions of hot water, transfer the residue onto the filter paper, and wash with hot water until the last washing does not respond to the Qualitative Tests (1) for sulfate. Place the residue and the filter paper in a platinum crucible, incinerate with strong heating, and ignite between 775°C and 825°C for 30 minutes, then cool, and weigh the residue as *a* (g). Moisten the residue with water, and add 6 mL of hydrofluoric acid and 3 drops of sulfuric acid. Evaporate to dryness, ignite for 5 minutes, cool, and weigh the residue as *b* (g).

$$\begin{aligned} &\text{Content (\% of silicon dioxide (SiO}_2\text{))} \\ &= \frac{a - b}{\text{mass (g) of the sample}} \times 100 \end{aligned}$$

(2) Magnesium oxide—Weigh accurately about 0.3 g of Magnesium Silicate, transfer to a 50-mL conical flask, add 10 mL of 0.5 mol/L sulfuric acid VS, and heat on a water bath for 15 minutes. Cool, transfer to a 100-mL volumetric flask, wash the conical flask with water, add the washings to the volumetric flask, dilute with water to 100 mL, and filter. Pipet 50 mL of the filtrate, shake with 50 mL of water and 5 mL of diluted 2,2',2''-nitrilotriethanol (1 in 2), add 2.0 mL of ammonia TS and 10 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).

$$\begin{aligned} &\text{Each mL of 0.05 mol/L disodium dihydrogen} \\ &\text{ethylenediamine tetraacetate VS} \\ &= 2.0152 \text{ mg of MgO} \end{aligned}$$

(3) Ratio of percentage (%) of magnesium oxide (MgO) to silicon dioxide (SiO₂)—Calculate the quotient from the percentages obtained in (1) and (2).

Containers and storage Containers—Well-closed containers.

Magnesium Sulfate

硫酸マグネシウム

MgSO₄·7H₂O: 246.47

Magnesium Sulfate, when ignited, contains not less than 99.0% of MgSO₄: 120.37.

Description Magnesium Sulfate occurs as colorless or white crystals. It has a cooling, saline, bitter taste.

It is very soluble in water, and practically insoluble in ethanol (95).

It dissolves in dilute hydrochloric acid.

Identification A solution of Magnesium Sulfate (1 in 40) responds to the Qualitative Tests for magnesium salt and for sulfate.

pH Dissolve 1.0 g of Magnesium Sulfate in 20 mL of water: the pH of this solution is between 5.0 and 8.2.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Magnesium Sulfate in 20 mL of water: the solution is clear and colorless.

(2) Chloride—Perform the test with 1.0 g of Magnesium Sulfate. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.014%).

(3) Heavy metals—Proceed with 2.0 g of Magnesium Sulfate according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Zinc—Dissolve 2.0 g of Magnesium Sulfate in 20 mL of water, and add 1 mL of acetic acid and 5 drops of potassium hexacyanoferrate (II) TS: no turbidity is produced.

(5) Calcium—Dissolve 1.0 g of Magnesium Sulfate in 5.0 mL of dilute hydrochloric acid, add water to make 100 mL, and use this solution as the sample solution. Separately, dissolve 1.0 g of Magnesium Sulfate in 2.0 mL of standard calcium solution and 5.0 mL of dilute hydrochloric acid, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with the sample solution and the standard solution as directed under the Atomic Absorption Spectrophotometry according to the following conditions, and determine the absorbances, *A_T* and *A_S*, of both solutions: *A_T* is not bigger than *A_S* - *A_T* (not more than 0.02%).

Gas: Combustible gas—Acetylene or hydrogen

Supporting gas—Air

Lamp: Calcium hollow-cathode lamp

Wavelength: 422.7 nm

(6) Arsenic—Prepare the test solution with 1.0 g of Magnesium Sulfate according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

Loss on ignition 45.0 - 52.0% (1 g, after drying at 105°C for 2 hours, ignite at 450°C for 3 hours).

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 MgSO₄

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 (MgSO₄·7H₂O: 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.

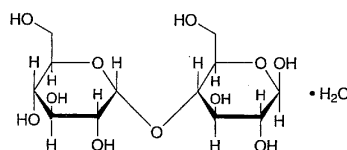
Assay Measure exactly a volume of Magnesium Sulfate Injection, equivalent to about 0.3 g of magnesium sulfate (MgSO₄·7H₂O), and add water to make 75 mL. Then add 5 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and proceed as directed in the Assay under Magnesium Sulfate.

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 12.324 mg of MgSO₄·7H₂O

Containers and storage Containers—Hermetic containers.

Maltose

マルトース



C₁₂H₂₂O₁₁·H₂O: 360.31
4-O- α -D-Glucopyranosyl- β -D-glucopyranose
monohydrate [6363-53-7]

Maltose, when dried, contains not less than 98.0% of C₁₂H₂₂O₁₁·H₂O.

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 [α]_D²⁰: +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).