(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.

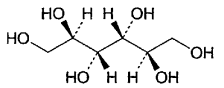
Selection of column: Dissolve 0.25 g of maltose, 0.25 g of glucose and 0.4 g of ethylene glycol in water to make 100 mL. Proceed with 20 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of maltose, glucose and ethylene glycol in this 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

mol/L hydrochloric acid VS (not more than 0.007%).

(4) Sulfate—Perform the test with 2.0 g of D-Mannitol. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.010%).

(5) Heavy metals—Proceed with 5.0 g of D-Mannitol according to Method 1, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 5 ppm).

(6) Nickel—Dissolve 0.5 g of D-Mannitol in 5 mL of water, add 3 drops of dimethylglyoxime TS and 3 drops of ammonia TS, and allow to stand for 5 minutes: no red color develops.

(7) Arsenic—Prepare the test solution with 1.5 g of D-Mannitol according to Method 1, and perform the test using Apparatus B (not more than 1.3 ppm).

(8) Sugars—To 5.0 g of D-Mannitol add 15 mL of water and 4.0 mL of dilute hydrochloric acid, and heat under a reflux condenser in a water bath for 3 hours. After cooling, neutralize with sodium hydroxide TS (indicator: 2 drops of methyl orange TS), and add water to make 50 mL. Pipet 10 mL of this solution into a flask, boil gently with 10 mL of water and 40 mL of Fehling's TS for 3 minutes, and allow to stand to precipitate copper (I) oxide. Filter the supernatant liquid through a glass filter (G4), wash the precipitate with hot water until the last washing no longer shows an alkaline reaction, and filter the washings through the glass filter described above. Dissolve the precipitate in 20 mL of iron (III) sulfate TS in the flask, filter through the glass filter described above, and wash the filter with water. Combine the washings and the filtrate, heat to 80°C, and titrate with 0.02 mol/L potassium permanganate: the consumed volume is not more than 1.0 mL.

Loss on drying Not more than 0.30% (1 g, 105°C, 4 hours).

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

Assay Weigh accurately about 0.2 g of D-Mannitol, previously dried, and dissolve in water to make exactly 100 mL. Pipet 10 mL of the solution into an iodine flask, add exactly 50 mL of potassium periodate TS, and heat for 15 minutes in a water bath. After cooling, add 2.5 g of potassium iodide, stopper tightly, and shake well. Allow to stand for 5 minutes in a dark place, and titrate with 0.1 mol/L sodium thiosulfate VS (indicator: 1 mL of starch TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium thiosulfate VS
= 1.8217 mg of $C_6H_{14}O_6$

Containers and storage Containers—Tight containers.

D-Mannitol Injection

D-Mannite Injection

D-マンニトール注射液

D-Mannitol Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of D-mannitol ($C_6H_{14}O_6$: 182.17).

Method of preparation Prepare as directed under Injections, with D-Mannitol. No preservative is added.

Description D-Mannitol Injection is a clear, colorless liquid. It has a sweet taste.

It may precipitate crystals.

Identification Concentrate D-Mannitol Injection on a water bath to make equal to the saturated solution. Proceed with 5 drops of this solution as directed in the Identification (1) under D-Mannitol.

pH 4.5 - 7.0

Residue on ignition Evaporate an exactly measured volume of D-Mannitol Injection, equivalent to 1.0 g of D-Mannitol, on a water bath to dryness, and perform the test: the mass of residue is not more than 1.0 mg.

Pyrogen Perform the test with D-Mannitol Injection stored in a container in a volume exceeding 10 mL: it meets the requirements of the Pyrogen Test.

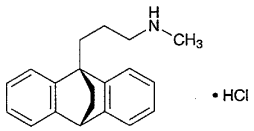
Assay Measure exactly a volume of D-Mannitol Injection, equivalent to about 5 g of D-Mannitol ($C_6H_{14}O_6$), and add water to make exactly 250 mL. To exactly 10 mL of this solution add water to make exactly 100 mL. Measure exactly 10 mL of this solution into an iodine flask, and proceed as directed in the Assay under D-Mannitol.

Each mL of 0.1 mol/L sodium thiosulfate VS
= 1.8217 mg of $C_6H_{14}O_6$

Containers and storage Containers—Hermetic containers.

Maprotiline Hydrochloride

塩酸マプロチリン



$C_{20}H_{23}N.HCl$: 313.86

N-[3-(9,10-Dihydro-9,10-ethanoanthracene-9-yl)propyl]-*N*-methylamine monohydrochloride [*10347-81-6*]

Maprotiline Hydrochloride, when dried, contains not less than 99.0% of $C_{20}H_{23}N.HCl$.

Description Maprotiline Hydrochloride occurs as a white crystalline powder.

It is soluble in methanol and in acetic acid (100), sparingly soluble in ethanol (99.5), and slightly soluble in water.

Melting point: about 244°C (with decomposition).

Identification (1) Determine the absorption spectrum of a solution of Maprotiline Hydrochloride in methanol (1 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelength.

(2) Determine the infrared absorption spectrum of Maprotiline Hydrochloride, previously dried, as directed in