

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<sub>6</sub>H<sub>14</sub>O<sub>6</sub>

**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<sub>6</sub>H<sub>14</sub>O<sub>6</sub>: 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.

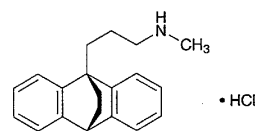
**Assay** Measure exactly a volume of D-Mannitol Injection, equivalent to about 5 g of D-Mannitol (C<sub>6</sub>H<sub>14</sub>O<sub>6</sub>), and add water to make exactly 250 mL. To exactly 10 mL of this solution add water to make exactly 100 mL. Measure exactly 10 mL of this solution into an iodine 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<sub>6</sub>H<sub>14</sub>O<sub>6</sub>

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

## Maprotiline Hydrochloride

塩酸マプロチリン



C<sub>20</sub>H<sub>23</sub>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<sub>20</sub>H<sub>23</sub>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