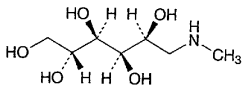
ethanol (95), evaporate on a water bath to dryness with thorough stirring, and dry at 105°C for 3 hours.

Containers and storage Containers—Well-closed containers.

Meglumine

メグルミン



$C_7H_{17}NO_5$: 195.21
1-Deoxy-1-methylamino-D-glucitol [*6284-40-8*]

Meglumine, when dried, contains not less than 99.0% of $C_7H_{17}NO_5$.

Description Meglumine occurs as a white, crystalline powder. It is odorless, and has a slightly bitter taste.

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

The pH of a solution of Meglumine (1 in 10) is between 11.0 and 12.0.

Identification (1) To 1 mL of a solution of Meglumine (1 in 10) add 1 mL of potassium 1,2-naphthoquinone-4-sulfonate TS: a deep red color develops.

(2) To 2 mL of a solution of Meglumine (1 in 10) add 1 drop of methyl red TS, and add 0.5 mL of dilute sodium hydroxide TS and 0.5 g of boric acid after neutralizing with 0.5 mol/L sulfuric acid TS: a deep red color develops.

(3) Dissolve 0.5 g of Meglumine in 1 mL of diluted hydrochloric acid (1 in 3), and add 10 mL of ethanol (99.5): a white precipitate is produced. Then, rubbing the inside wall of the container with a glass rod, cool with ice and produce more precipitate. Filter the precipitate by suction through a glass filter (G3), wash the precipitate with a small volume of ethanol (99.5), and dry at 105°C for 1 hour: the residue thus obtained melts between 149°C and 152°C.

Optical rotation $[\alpha]_D^{20}$: −16.0 – −17.0° (after drying, 1 g, water, 10 mL, 100 mm).

Melting point 128 – 131°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Meglumine in 10 mL of water: the solution is clear and colorless.

(2) Chloride—Dissolve 1.0 g of Meglumine in 30 mL of water, and add 10 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.009%).

(3) Sulfate—Dissolve 1.0 g of Meglumine in 30 mL of water, and add 5 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.019%).

(4) Heavy metals—Proceed with 2.0 g of Meglumine according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(5) Arsenic—Prepare the test solution with 2.0 g of Meglumine according to Method 3, and perform the test using Apparatus B (not more than 1 ppm).

(6) Reducing substances—To 5 mL of a solution of Meglumine (1 in 20) add 5 mL of Fehling's TS, and boil for 2 minutes: no red-brown precipitate is produced.

Loss on drying Not more than 0.5% (1 g, 105°C, 4 hours).

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

Assay Weigh accurately about 0.4 g of Meglumine, previously dried, dissolve in 25 mL of water, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: 2 drops of methyl red TS).

Each mL of 0.1 mol/L hydrochloric acid VS
= 19.522 mg of $C_7H_{17}NO_5$

Containers and storage Containers—Tight containers.

Mentha Herb

Menthae Herba

ハッカ

Mentha Herb is the terrestrial part of *Mentha arvensis* Linné var. *piperascens* Malinvaud (*Labiatae*).

Description Stem with opposite leaves; stem, square, light brown to red-purple in color, and with fine hairs; when smoothed by immersing in water, leaf, ovate to oblong, with acute apex and base, 2 – 8 cm in length, 1 – 2.5 cm in width, margin irregularly serrated; the upper surface, light brown-yellow to light green-yellow, and the lower surface, light green to light green-yellow in color; petiole 0.3 – 1 cm in length. Under a magnifying glass, leaf reveals hairs, glandular hairs and scales. It has a characteristic aroma and gives a cool feeling on keeping in the mouth.

Identification To 1 mL of the mixture of essential oil and xylene, obtained in the Essential oil content, add carefully 2 mL of sulfuric acid to make two layers: a deep red to red-brown color develops at the zone of contact.

Purity Foreign matter—The amount of roots and other foreign matter contained in Mentha Herb does not exceed 2.0%.

Loss on drying Not more than 15.0% (6 hours).

Total ash Not more than 11.0%.

Acid-insoluble ash Not more than 2.5%.

Essential oil content Perform the test with 50.0 g of pulverized Mentha Herb as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.4 mL.