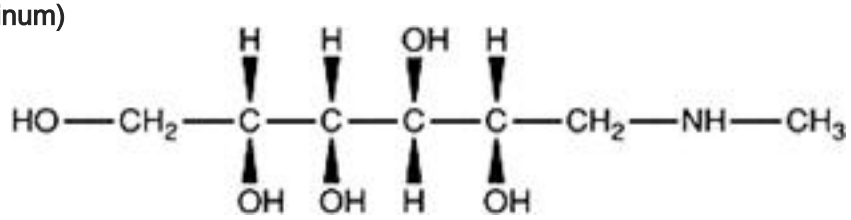
Meglumine (Megluminum)



$C_7H_{17}NO_5$

Relative molecular mass. 195.2

Chemical name. 1-Deoxy-1-(methylamino)-D-glucitol; CAS Reg. No. 6284-40-8.

Description. A white or almost white, crystalline powder; odourless or almost odourless.

Solubility. Freely soluble in water; slightly soluble in ethanol (~750 g/l) TS; practically insoluble in ether R.

Category. Used in the preparation of meglumine amidotrizoate and meglumine iotroxate as radiocontrast media.

Storage. Meglumine should be kept in a well-closed container.

Requirements

Meglumine contains not less than **99.0%** and not more than the equivalent of **100.5%** of $C_7H_{17}NO_5$, calculated with reference to the dried substance.

Identity tests

A. To 5 mL of water add 0.5 mL of paraldehyde R and 0.5 mL of sulfuric acid (~190 g/l) TS. Shake and warm carefully until a cloudy solution appears, then allow to cool for 15 minutes. Freshly prepare a solution containing 0.1 g of sodium nitroprusside R per mL and to 0.2 mL add 1 mL of the above solution, then add 50 mg of Meglumine and 2 mL of a solution of 50 mg of sodium tetraborate R per mL; a blue colour develops slowly which becomes more intense with time.

B. Dissolve 0.2 g in 2 mL of water, add 0.05 mL of methyl red/ethanol TS, and neutralize with sulfuric acid (0.25 mol/l) VS. Add 1 mL of sodium hydroxide (0.1 mol/l) VS and 1 g of boric acid R; the solution becomes acidic.

Melting range. 128-131 °C.

Specific optical rotation. Use a 0.10 g/mL solution; $[\alpha]_D^{20\,°C}$ = -15.7° to -17.3°.

Heavy metals. Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 1; determine the heavy metals content according to Method A; not more than 20 µg/g.

Reducing sugars. Dissolve 0.25 g in 5 mL of water, add 5 mL of potassio-cupric tartrate TS and boil for 2 minutes; no red-brown precipitate is produced.

Clarity and colour of solution. A solution of 1 g in 10 mL of water is clear and colourless.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry to constant mass at 105 °C; it loses not more than 10 mg/g.

Assay. Dissolve about 0.5 g, accurately weighed, in 40 mL of water and titrate with hydrochloric acid (0.1 mol/l) VS, using methyl red/ethanol TS as indicator.

Each mL of hydrochloric acid (0.1 mol/l) VS is equivalent to 19.52 mg of $C_7H_{17}NO_5$.

Additional requirement for Meglumine for parenteral use

Complies with the monograph for "Parenteral preparations".

Pyrogens. Carry out the test as described under 3.5 Test for pyrogens, injecting, per kg of the rabbit's mass, a solution in sterile water R containing 0.6 g of Meglumine in not more than 5 mL.

Additional requirement for Meglumine for sterile use

Complies with 3.2 Test for sterility.