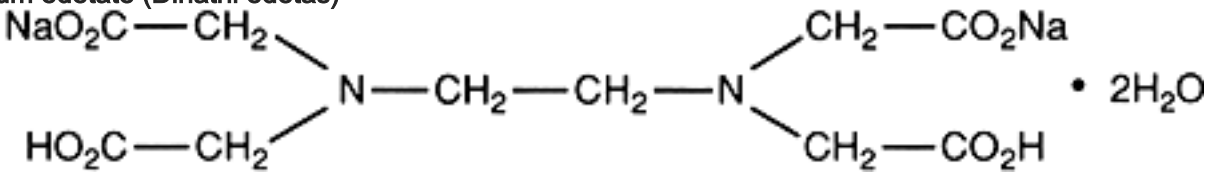
Disodium edetate (Dinatrii edetas)



$C_{10}H_{14}N_2Na_2O_8,2H_2O$

Relative molecular mass. 372.2

Chemical name. Disodium dihydrogen (ethylenedinitrilo)tetraacetate dihydrate; *N,N'*-1,2-ethanediylbis[*N*-(carboxymethyl)glycine] disodium salt, dihydrate; CAS Reg. No. 6381-92-6.

Other name. Edetate disodium.

Description. A white, crystalline powder; odourless.

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

Category. Stabilizer; chelating agent.

Storage. Disodium edetate should be kept in a well-closed container.

Additional information. Solutions of disodium edetate should not come into contact with metal.

Requirements

Disodium edetate contains not less than **98.5%** and not more than the equivalent of **101.0%** of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.

Identity tests

• Either test A alone or tests B, C, and D may be applied.

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from disodium edetate R or with the *reference spectrum* of disodium edetate.

B. To 3 drops of ferric chloride (25 g/l) TS add 3 drops of ammonium thiocyanate (75 g/l) TS; to the deep red solution produced add 0.05 g of Disodium edetate; the colour is discharged, leaving a yellowish solution. (Keep this solution for test D.)

C. Dissolve 2 g in 25 mL of water, add 2 mL of lead nitrate (100 g/l) TS, shake, and add 6 mL of potassium iodide (80 g/l) TS; no yellow precipitate is observed.

D. To the solution from test B, add ammonia (~100 g/l) TS, drop by drop, until an alkaline reaction is obtained with pH-indicator paper R. Add 5 mL of ammonium oxalate (25 g/l) TS; no precipitate is produced (distinction from sodium calcium edetate).

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 3; determine the heavy metals content according to Method A; not more than 20 µg/g.

pH value. pH of a 0.05 g/mL solution, 4.0-5.5.

Assay. Dissolve 0.5 g, accurately weighed, in sufficient water to produce 300 mL. Add 2 g of methenamine R and 2 mL of hydrochloric acid (~70 g/l) TS. Titrate with lead nitrate (0.1 mol/l) VS to which 50 mg of xylenol orange indicator mixture R has been added.

Each mL of lead nitrate (0.1 mol/l) VS is equivalent to 37.22 mg of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.