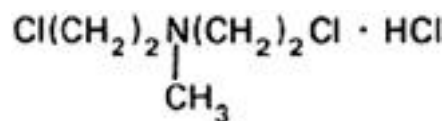


**Chlormethine hydrochloride (Chlormethini hydrochloridum)****Molecular formula.**  $C_5H_{11}Cl_2N, HCl$ **Relative molecular mass.** 192.5**Graphic formula.****Chemical name.** 2,2'-Dichloro-*N*-methyldiethylamine hydrochloride; 2-chloro-*N*-(2-chloroethyl)-*N*-methylethanamine hydrochloride; CAS Reg. No. 55-86-7.**Description.** A white or almost white, crystalline powder.**Solubility.** Very soluble in water; soluble in ethanol (~750 g/l) TS.**Category.** Antineoplastic.**Storage.** Chlormethine hydrochloride should be kept in a tightly closed container and stored at a cool temperature.**Additional information.** CAUTION: Chlormethine hydrochloride is vesicant, it must be handled with care avoiding contact with the skin and inhaling airborne particles. It is hygroscopic.**Requirements****Definition.** Chlormethine hydrochloride contains not less than 98.0% and not more than 101.0% of  $C_5H_{11}Cl_2N, HCl$ , calculated with reference to the anhydrous substance.**Identity tests**

- A. Dissolve 0.05 g in 5 mL of water and add 0.02 mL of potassio-mercuric iodide TS; a cream-coloured precipitate is produced.
- B. Add 0.1 g to 1 mL of sodium thiosulfate (0.1 mol/l) VS contained in a test-tube. Shake, allow to stand for 2 hours, and add 1 drop of iodine TS; the colour of free iodine remains.
- C. Melting temperature, about 110°C with decomposition.

**Clarity of solution.** A solution of 0.10 g in 10 mL of carbon-dioxide-free water R is clear.**Sulfated ash.** Not more than 1.0 mg/g.**Water.** Determine as described under [2.8 Determination of water by the Karl Fischer method](#), Method A, using about 1 g of the substance; the water content is not more than 5.0 mg/g.**pH value.** pH of a 2.0 mg/mL solution, 3.0-5.0.**Assay.** To about 0.20 g, accurately weighed, add 15 mL of potassium hydroxide/ethanol (1 mol/l) VS and 15 mL of water. Boil under a reflux condenser for 2 hours, and evaporate the solution to half its volume on a water-bath. Dilute to 150 mL with water, add 3 mL of nitric acid (~1000 g/l) TS and 50 mL of silver nitrate (0.1 mol/l) VS. Shake vigorously and filter. Wash the precipitate with water and titrate the excess of silver nitrate in the combined filtrate and washings with ammonium thiocyanate (0.1 mol/l) VS, using 2.5 mL of ferric ammonium sulfate (45 g/l) TS as indicator. Each mL of silver nitrate (0.1 mol/l) VS is equivalent to 6.417 mg of  $C_5H_{11}Cl_2N, HCl$ .