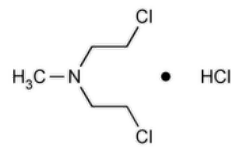


Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-FF596422-47F9-4B2D-8C2A-0B05023D6BDD_2_en-US
DOI: https://doi.org/10.31003/USPNF_M47750_02_01
DOI Ref: m8wc1

© 2025 USPC
Do not distribute

Mechlorethamine Hydrochloride



$C_5H_{11}Cl_2N \cdot HCl$ 192.51
Ethanamine, 2-chloro-*N*-(2-chloroethyl)-*N*-methyl-, hydro chloride.
2,2'-Dichloro-*N*-methyl-diethylamine hydrochloride CAS RN®: 55-86-7; UNII: L0MR697HHI.

» Mechlorethamine Hydrochloride contains not less than 97.5 percent and not more than 100.5 percent of $C_5H_{11}Cl_2N \cdot HCl$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers.
Labeling—The label bears a warning that great care should be taken to prevent inhaling particles of Mechlorethamine Hydrochloride and exposing the skin to it.

USP Reference Standards (11)—
[USP Mechlorethamine Hydrochloride RS](#)

Identification—

Change to read:
A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020) ·
B: Transfer 100 mg to a test tube containing 1 mL of sodium thiosulfate solution (prepared by dissolving 1 g of sodium thiosulfate and 100 mg of sodium carbonate in 40 mL of water), shake, allow to stand for 2 hours, then add 1 drop of iodine TS: the color of free iodine remains.
MELTING RANGE (741): between 108° and 111°.
pH (791): between 3.0 and 5.0, in a solution (1 in 500).
WATER DETERMINATION, Method I (921): not more than 0.4%.
Ionic chloride content—Dissolve about 30 mg, accurately weighed, in 30 mL of water contained in a beaker. Add 5 mL of nitric acid and stir. Titrate with 0.02 N silver nitrate VS to a potentiometric endpoint, using a silver combination electrode. Perform a blank determination (see [Titrimetry \(541\)](#)), and make any necessary correction. Each mL of 0.02 N silver nitrate is equivalent to 0.709 mg of ionic chloride: not less than 18.0% and not more than 19.3% of ionic chloride is found.
Assay—Transfer about 100 mg of Mechlorethamine Hydrochloride, accurately weighed, to a 125-mL conical flask. Add 100 mg of sodium bicarbonate and 20.0 mL of 0.1 N sodium thiosulfate VS. Allow to stand for 2½ hours, add 3 mL of starch TS, and titrate the excess sodium thiosulfate with 0.1 N iodine VS. Each mL of 0.1 N sodium thiosulfate is equivalent to 9.626 mg of $C_5H_{11}Cl_2N \cdot HCl$.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MECHLORETHAMINE HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 29(3)

Current DocID: GUID-FF596422-47F9-4B2D-8C2A-0B05023D6BDD_2_en-US
DOI: https://doi.org/10.31003/USPNF_M47750_02_01
DOI ref: [m8wc1](#)