

Status: Currently Official on 15-Feb-2025  
Official Date: Official as of 01-May-2018  
Document Type: USP Monographs  
DocId: GUID-C41FE3B3-1C77-4B5E-8E6A-8E82A21132AD\_3\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M47780\\_03\\_01](https://doi.org/10.31003/USPNF_M47780_03_01)  
DOI Ref: ts2a3

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# Mechlorethamine Hydrochloride for Injection

» Mechlorethamine Hydrochloride for Injection is a sterile mixture of Mechlorethamine Hydrochloride with Sodium Chloride or other suitable diluent. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of mechlorethamine hydrochloride ( $C_5H_{11}Cl_2N \cdot HCl$ ).

**Packaging and storage**—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#), [Packaging for constitution](#).

**Labeling**—It meets the requirements for [Labeling \(7\)](#), [Labels and Labeling for Injectable Products](#). The label bears a warning that great care should be taken to prevent inhaling particles of Mechlorethamine Hydrochloride for Injection and exposing the skin to it.

**USP REFERENCE STANDARDS (11)**—

[USP Mechlorethamine Hydrochloride RS](#)

**COMPLETENESS OF SOLUTION (641)**—A 0.10-g portion dissolves in 10 mL of carbon dioxide-free water to yield a clear solution.

**Constituted solution**—At the time of use, it meets the requirements for [Injections and Implanted Drug Products \(1\)](#), [Specific Tests](#), [Completeness and clarity of solutions](#).

**Identification**—It meets the requirements of the *Identification* tests under [Mechlorethamine Hydrochloride](#).

**BACTERIAL ENDOTOXINS TEST (85)**—It contains not more than 12.5 USP Endotoxin Units per mg of mechlorethamine hydrochloride.

**pH (791)**: between 3.0 and 5.0, in a solution (1 in 50).

**WATER DETERMINATION, Method I (921)**: not more than 1.0%.

**PARTICULATE MATTER IN INJECTIONS (788)**: meets the requirements for small-volume injections.

**Other requirements**—It meets the requirements for [Sterility Tests \(71\)](#) and [Uniformity of Dosage Units \(905\)](#).

**Assay**—

*Assay preparation*—Select a counted number of not fewer than 10 containers of Mechlorethamine Hydrochloride for Injection, equivalent to about 100 mg of mechlorethamine hydrochloride. Dissolve the contents of each container in water, and transfer the resulting solutions to a 250-mL conical flask.

*Procedure*—Immediately proceed as directed in the Assay under [Mechlorethamine Hydrochloride](#), beginning with “Add 100 mg of sodium bicarbonate.” Calculate the average content, in mg, of mechlorethamine hydrochloride ( $C_5H_{11}Cl_2N \cdot HCl$ ) per container of Mechlorethamine Hydrochloride for Injection taken by the formula:

$$9.626(V/N)$$

in which *V* is the volume, in mL, of 0.1 N sodium thiosulfate consumed; and *N* is the number of containers selected to prepare the Assay preparation.

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

| Topic/Question                              | Contact                                                                     | Expert Committee          |
|---------------------------------------------|-----------------------------------------------------------------------------|---------------------------|
| MECHLORETHAMINE HYDROCHLORIDE FOR INJECTION | <a href="#">Documentary Standards Support</a>                               | SM32020 Small Molecules 3 |
| REFERENCE STANDARD SUPPORT                  | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM32020 Small Molecules 3 |

**Chromatographic Database Information:** [Chromatographic Database](#)

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**Current DocID: GUID-C41FE3B3-1C77-4B5E-8E6A-8E82A21132AD\_3\_en-US**

**Previous DocID: GUID-C41FE3B3-1C77-4B5E-8E6A-8E82A21132AD\_1\_en-US**

**DOI: [https://doi.org/10.31003/USPNE\\_M47780\\_03\\_01](https://doi.org/10.31003/USPNE_M47780_03_01)**

**DOI ref: [ts2a3](#)**

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