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# Edrophonium Chloride Injection

» Edrophonium Chloride Injection is a sterile solution of Edrophonium Chloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of  $C_{10}H_{16}ClNO$ .

**Packaging and storage**—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass.

**Labeling**—Label the Injection in multiple-dose containers to indicate an expiration date of not later than 3 years after the date of manufacture, and label the Injection in single-dose containers to indicate an expiration date of not later than 4 years after the date of manufacture.

**USP REFERENCE STANDARDS (11)**.—  
[USP Edrophonium Chloride RS](#)

**Identification**—

**Change to read:**

**A:** ▲ [Spectroscopic Identification Tests \(197\)](#). [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-May-2020) —Test solution versus standard solution prepared as directed in the Assay.

**B:** Place in a small separator a volume of Injection, equivalent to about 30 mg of edrophonium chloride, add 15 mL of pH 9.6 alkaline borate buffer (see [Buffer Solutions](#) in the section [Reagents, Indicators, and Solutions](#)) and 5 mL of a 1 in 1000 solution of thymol blue in pH 9.6 alkaline borate buffer, and mix. Add 10 mL of chloroform, shake thoroughly, and allow to settle: a yellow color is produced in the chloroform layer.

**C:** It responds to the tests for [Chloride \(191\)](#).

**BACTERIAL ENDOTOXINS TEST (85)**.—It contains not more than 8.33 USP Endotoxin Units per mg of edrophonium chloride.

**pH (791)**: between 5.0 and 5.8.

**Other requirements**—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

**Assay**—Pipet a volume of Injection, equivalent to about 50 mg of edrophonium chloride, into a glass-stoppered, 50-mL centrifuge tube. Add 5 mL of pH 8.0 phosphate buffer (see [Buffer Solutions](#) in the section [Reagents, Indicators, and Solutions](#)) and 5 g of sodium chloride. Wash the solution with four 20-mL portions of a mixture of equal volumes of solvent hexane and ether. Transfer the aqueous phase to a 100-mL volumetric flask, add 0.1 N hydrochloric acid to volume, and mix. Transfer a 5-mL aliquot of this solution to a 50-mL volumetric flask, add 0.1 N hydrochloric acid to volume, and mix test solution. Dissolve an accurately weighed quantity of [USP Edrophonium Chloride RS](#) in 0.1 N hydrochloric acid, and dilute quantitatively and stepwise with the acid to obtain a Standard solution having a known concentration of about 50 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 273 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of  $C_{10}H_{16}ClNO$  in each mL of the Injection taken by the formula:

$$(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of [USP Edrophonium Chloride RS](#) in the Standard solution; V is the volume, in mL, of Injection taken; and  $A_U$  and  $A_S$  are the absorbances of the test solution and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
EDROPHONIUM CHLORIDE INJECTION	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

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

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