## **Quality standards**

Edition: BP 2025 (Ph. Eur. 11.6 update)

# **Edrophonium Injection**

**General Notices** 

#### Action and use

Cholinesterase inhibitor.

## **DEFINITION**

Edrophonium Injection is a sterile solution of Edrophonium Chloride in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

# Content of edrophonium chloride, C<sub>10</sub>H<sub>16</sub>CINO

95.0 to 105.0% of the stated amount.

## **IDENTIFICATION**

- A. Dilute a sufficient volume of the injection with 0.1 M <u>sodium hydroxide</u> to give a solution containing 0.001% w/v of Edrophonium Chloride. The <u>light absorption</u> of the resulting solution, <u>Appendix II B</u>, in the range 220 to 350 nm exhibits two maxima, at 240 nm and 294 nm. The <u>absorbances</u> at the maxima are about 1.1 and about 0.34 respectively.

  B. To a volume containing 20 mg of Edrophonium Chloride add 0.05 ml. of <u>iron(w)</u> chloride solution R1. A reddish violet
- B. To a volume containing 20 mg of Edrophonium Chloride add 0.05 mL of <u>iron(III) chloride solution R1</u>. A reddish violet colour is produced.
- C. Yields reaction A characteristic of chlorides, Appendix VI.

#### **TESTS**

#### **Acidity**

pH, 5.0 to 6.0, Appendix V L.

### Dimethylaminophenol

To a volume containing 50 mg of Edrophonium Chloride add 10 mL of <u>phosphate buffer pH 8.0</u> and extract with two 20 mL quantities of <u>chloroform</u>. Wash the extracts successively with two 10 mL quantities of <u>water</u>, extract with 10 mL of 0.1m <u>sodium hydroxide</u> and discard the chloroform. The <u>absorbance</u> of the resulting solution at 293 nm is not more than 0.125, <u>Appendix II B</u>.

#### **ASSAY**

To a volume containing 50 mg of Edrophonium Chloride add sufficient <u>water</u> to produce 100 mL. Dilute 10 mL of this solution to 100 mL with <u>water</u> and measure the <u>absorbance</u> of the resulting solution at the maximum at 273 nm, <u>Appendix</u>

 $\frac{\text{https://nhathuocngocanh.com/bp/}}{\text{II B.}} \ \text{Calculate the content of C}_{10} \ \text{H}_{16} \ \text{CINO taking 110 as the value of } A \ (1\%, \ 1\ \text{cm}) \ \text{at the maximum at 273 nm.}$ 

# **STORAGE**

Edrophonium Injection should be protected from light.