Quality standards

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

Alimemazine Tablets

General Notices

Action and use

Histamine H₁ receptor antagonist; antihistamine.

DEFINITION

Alimemazine Tablets contain Alimemazine Tartrate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of alimemazine tartrate, C₃₆H₄₄N₄S₂,C₄H₆O₆

92.5 to 107.5% of the stated amount.

IDENTIFICATION

- A. To a quantity of the powdered tablets containing 40 mg of Alimemazine Tartrate add 10 mL of <u>water</u> and 2 mL of 1M <u>sodium hydroxide</u>, shake and extract with 15 mL of <u>ether</u>. Wash the ether layer with 5 mL of <u>water</u>, dry with <u>anhydrous sodium sulfate</u> and evaporate the ether to dryness. Dissolve the residue in 0.4 mL of <u>dichloromethane</u>. The <u>infrared absorption spectrum</u> of the resulting solution, <u>Appendix II A</u>, is concordant with the <u>reference spectrum</u> of alimemazine (<u>RS</u> 005).
- B. To a quantity of the powdered tablets containing 1 mg of Alimemazine Tartrate add 1 mL of a mixture of equal volumes of <u>formaldehyde solution</u> and <u>sulfuric acid</u>. A purple colour is produced.

TESTS

Related substances

Comply with the test for <u>related substances in phenothiazines</u>, <u>Appendix III A</u>, using <u>mobile phase A</u> and applying separately to the plate 20 µL of each of the following freshly prepared solutions. For solution (1) extract a quantity of the powdered tablets containing 0.1 g of Alimemazine Tartrate with 10 mL of a mixture of 95 volumes of <u>methanol</u> and 5 volumes of <u>diethylamine</u> and filter. For solution (2) dilute 1 volume of solution (1) to 200 volumes with the same solvent mixture.

ASSAY

Carry out the following procedure protected from light. Add 150 mL of <u>0.1m hydrochloric acid</u> to 10 tablets, shake for 10 minutes, mix with the aid of ultrasound for 1 minute, dilute with <u>0.1m hydrochloric acid</u> to produce a solution containing 0.050% w/v of Alimemazine Tartrate and filter (solution A). Dilute 10 mL of solution A to 100 mL with <u>water</u> (solution B). To a further 10 mL of solution A add 2 mL of <u>peroxyacetic acid solution</u>, mix, allow to stand for 5 minutes and add sufficient <u>water</u> to produce 100 mL (solution C). Measure the <u>absorbance</u> of solution C at the maximum at 342 nm, <u>Appendix II B</u>,

https://nhathuocngocanh.com/bp/using solution B in the reference cell and measure the <u>absorbance</u> of solution B at the same wavelength using <u>water</u> in the reference cell. Repeat the procedure using a 0.05% w/v solution of alimemazine tartrate BPCRS in 0.1M hydrochloric acid in place of solution A, beginning at the words 'Dilute 10 mL of solution A ...' and calculate the content of C₃₆H₄₄N₄S₂,C₄H₆O using the declared content of $C_{36}H_{44}N_4S_2$, C_4H_6O in <u>alimemazine tartrate BPCRS</u>. The test is not valid if the absorbance of solution B is more than 0.10.