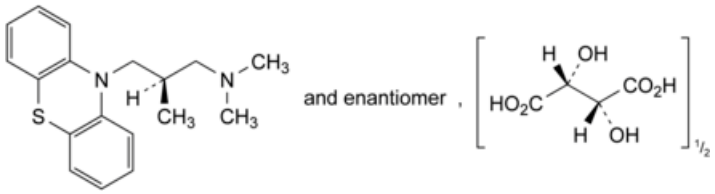
Edition: BP 2025 (Ph. Eur. 11.6 update)

Alimemazine Tartrate

General Notices

(Alimemazine Hemitartrate Ph. Eur. monograph 2650)



$C_{20}H_{25}N_2O_3S$ 373.5 *4330-99-8*

Action and use

Histamine H_1, receptor antagonist; sedative.

Preparations

Paediatric Alimemazine Oral Solution

Strong Paediatric Alimemazine Oral Solution

Alimemazine Tablets

Ph Eur

DEFINITION

(*2RS*)-*N,N,*2-Trimethyl-3-(10*H*-phenothiazin-10-yl)propan-1-amine hemi[(2*R*,3*R*)-2,3-dihydroxybutanedioate].

Content

99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or very slightly yellowish powder.

Solubility

Freely soluble in water, sparingly soluble in ethanol (96 per cent), practically insoluble in toluene.

It deteriorates when exposed to air and light.

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison alimemazine hemitartrate CRS.

TESTS

Appearance of solution

The solution is not more opalescent than reference suspension II (2.2.1) and not more intensely coloured than reference solution BY_5 (2.2.2, Method II).

Dissolve 1.0 g in water R and dilute to 10 mL with the same solvent.

pH (2.2.3)

5.0 to 6.5. *Carry out the test protected from light and use a freshly prepared solution.*

Dissolve 1.0 g in carbon dioxide-free water R and dilute to 50 mL with the same solvent.

Related substances

Liquid chromatography (2.2.29). *Carry out the test protected from light and use freshly prepared solutions.*

Solvent mixture acetonitrile R, water R (20:80 *V/V*).

Test solution Dissolve 35 mg of the substance to be examined in the solvent mixture and dilute to 100.0 mL with the solvent mixture.

Reference solution (a) Dilute 1.0 mL of the test solution to 100.0 mL with the solvent mixture. Dilute 1.0 mL of this solution to 10.0 mL with the solvent mixture.

Reference solution (b) Dissolve 3.5 mg of alimemazine for system suitability CRS (containing impurities A, B and C) in the solvent mixture and dilute to 10.0 mL with the solvent mixture.

Column:

— *size*: *l* = 0.15 m, *Ø* = 4.6 mm;

— *stationary phase*: base-deactivated end-capped octadecylsilyl silica gel for chromatography R (3 µm);

— *temperature*: 40 °C.

Mobile phase acetonitrile R, methanol R, 3.854 g/L solution of ammonium acetate R (10:40:50 *V/V/V*).

Flow rate 1.3 mL/min.

Detection Spectrophotometer at 253 nm.

Injection 20 µL.

Run time Twice the retention time of alimemazine.

Identification of impurities Use the chromatogram supplied with alimemazine for system suitability CRS and the chromatogram obtained with reference solution (b) to identify the peaks due to impurities A, B and C.

Relative retention With reference to alimemazine (retention time = about 27 min): impurity A = about 0.1; impurity B = about 0.5; impurity C = about 1.4.

System suitability Reference solution (b):

— resolution: minimum 5.0 between the peaks due to alimemazine and impurity C.

Calculation of percentage contents:

— *correction factors*: multiply the peak areas of the following impurities by the corresponding correction factor: impurity A = 4.4; impurity C = 0.4;

— for each impurity, use the concentration of alimemazine hemitartrate in reference solution (a).

Limits:

— *impurity B*: maximum 0.3 per cent;

— *impurities A, C*: for each impurity, maximum 0.15 per cent;

— *unspecified impurities*: for each impurity, maximum 0.10 per cent;

— *total*: maximum 0.5 per cent;

— *reporting threshold*: 0.05 per cent.

Loss on drying (*2.2.32*)

Maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C for 3 h.

Sulfated ash (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.300 g in 50 mL of *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

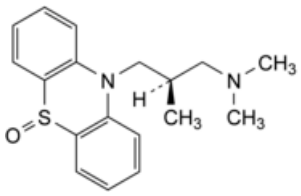
1 mL of *0.1 M perchloric acid* is equivalent to 37.35 mg of $C_{20}H_{25}N_2O_3S$.

STORAGE

In an airtight container, protected from light.

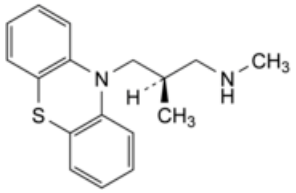
IMPURITIES

Specified impurities *A, B, C.*



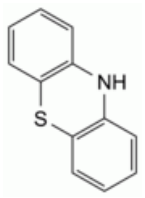
and enantiomer

A. (2*RS*)-*N*,*N*,2-trimethyl-3-(5-oxido-10*H*-phenothiazin-10-yl)propan-1-amine,



and enantiomer

B. (2*RS*)-*N*,2-dimethyl-3-(10*H*-phenothiazin-10-yl)propan-1-amine,



C. 10*H*-phenothiazine.

Ph Eur