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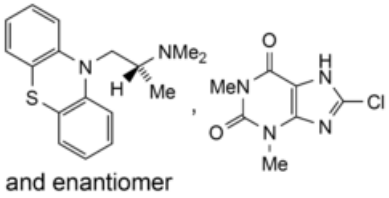
Promethazine Teoclate

General Notices



and enantiomer

$C_{17}H_{20}N_2S,C_7H_7ClN_4O_2$ 499.0 *17693-51-5*

Action and use

Histamine H_1 receptor antagonist; antihistamine.

Preparation

Promethazine Teoclate Tablets

DEFINITION

Promethazine Teoclate is the (*RS*)-dimethyl(2-phenothiazin-10-ylpropyl)amine salt of 8-chlorotheophylline. It contains not less than 98.0% and not more than 101.0% of $C_{17}H_{20}N_2S,C_7H_7ClN_4O_2$, calculated with reference to the dried substance.

CHARACTERISTICS

A white or almost white powder.

Very slightly soluble in *water*; sparingly soluble in *ethanol (96%)*; practically insoluble in *ether*.

IDENTIFICATION

A. Shake 0.15 g with 2.5 mL of *water*, add 1 mL of 5M *ammonia* and extract with 30 mL of *ether*. Wash the ether extract with 10 mL of *water*, dry with *anhydrous sodium sulfate* and evaporate the ether to dryness. Dissolve the residue in 1 mL of *chloroform IR*. The *infrared absorption spectrum* of the resulting solution, Appendix II A, is concordant with the *reference spectrum* of promethazine *(RS 297)*.
B. Dissolve 5 mg in 2 mL of *sulfuric acid* and allow to stand for 5 minutes. A red colour is produced.
C. Shake 0.4 g with 10 mL of *water*, add 4 mL of 5M *ammonia*, shake with two 30-mL quantities of *ether* and add 4 mL of *hydrochloric acid* to the aqueous solution. Filter the white precipitate, wash with *water* and dry at 105°. Dissolve 10 mg of the residue in 1 mL of *hydrochloric acid*, add 0.1 g of *potassium chlorate* and evaporate to dryness. A reddish residue remains which becomes purple on exposure to the vapour of ammonia.

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TESTS

Chloride

Shake 0.3 g with 30 mL of *water* for 2 minutes and filter. 15 mL of the filtrate complies with the *limit test for chlorides*, Appendix VII, but using 2 mL of *nitric acid* in place of the 1 mL of *dilute nitric acid* (350 ppm).

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 5 volumes of *diethylamine*, 10 volumes of *acetone* and 85 volumes of *cyclohexane* as the mobile phase. Pour the mobile phase into an unlined tank, immediately place the prepared plate in the tank, close the tank and allow the solvent front to ascend 12 cm above the line of application. Apply separately to the plate 10 µL of each of the following solutions in a mixture of 5 volumes of *diethylamine* and 95 volumes of *methanol*. Solution (1) contains 2% w/v of the substance being examined. Solution (2) contains 0.02% w/v of *isopromethazine hydrochloride BPCRS*. For solution (3) dilute 1 volume of solution (1) to 200 volumes. For solution (4) dilute 1 volume of solution (1) to 500 volumes. Allow the plate to dry in air and examine under *ultraviolet light (254 nm)*. In the chromatogram obtained with solution (1) any spot corresponding to isopromethazine is not more intense than the spot in the chromatogram obtained with solution (2) (1%), any other *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (3) (0.5%) and not more than three such spots are more intense than the spot in the chromatogram obtained with solution (4) (0.2%). Disregard any spot remaining on the line of application.

Loss on drying

When dried to constant weight at 105°, loses not more than 0.5% of its weight. Use 1 g.

Sulfated ash

Not more than 0.1%, Appendix IX A.

ASSAY

Dissolve 1 g in 200 mL of *acetone* and carry out Method I for *non-aqueous titration*, Appendix VIII A, using 3 mL of a saturated solution of *methyl orange* in *acetone* as indicator. Each mL of *0.1M perchloric acid VS* is equivalent to 49.90 mg of $C_{17}H_{20}N_2S,C_7H_7ClN_4O_2$.

STORAGE

Promethazine Teoclate should be protected from light.