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

Dicycloverine Tablets

General Notices

Action and use

Anticholinergic.

DEFINITION

Dicycloverine Tablets contain Dicycloverine Hydrochloride.

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

Content of dicycloverine hydrochloride, $C_{19}H_{35}NO_2$,HCl

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Extract a quantity of the powdered tablets containing 0.2 g of Dicycloverine Hydrochloride with 20 mL of *chloroform*, filter, evaporate the filtrate to dryness, recrystallise the residue from *acetone* and dry at 105° for 4 hours. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of dicycloverine hydrochloride *(RS 098)*.
B. Shake a quantity of the powdered tablets containing 10 mg of Dicycloverine Hydrochloride with 5 mL of *water* and 0.2 mL of 2M *nitric acid*, filter and add 0.5 mL of *silver nitrate solution* to the filtrate. A white precipitate is produced.

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 0.2 g of Dicycloverine Hydrochloride with 8 mL of *water* and 2 mL of 13.5M *ammonia*, extract with two 20-mL quantities of *dichloromethane*, shake with *anhydrous sodium sulfate*, filter (Whatman 1PS paper is suitable), evaporate the filtrate to dryness and dissolve the residue in 4 mL of *dichloromethane*.
(2) Dilute 1 volume of solution (1) to 500 volumes with *dichloromethane*.
(3) 0.1% w/v of each of *dicycloverine hydrochloride BPCRS* and *tropicamide BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *TLC silica gel G plate*.
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in a current of warm air and spray with *dilute potassium iodobismuthate solution*.

MOBILE PHASE

5 volumes of 13.5M *ammonia*, 10 volumes of *ethyl acetate*, 10 volumes of *water* and 75 volumes of *propan-1-ol*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows two clearly separated spots.

LIMITS

In the chromatogram obtained with solution (1), any *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (2) (0.2%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 30 mg of Dicycloverine Hydrochloride add 20 mL of *water* and shake. Add 10 mL of 1M *sulfuric acid*, 1 mL of *dimethyl yellow solution* and 40 mL of *chloroform*, shake and titrate with 0.004M *sodium dodecyl sulfate VS*, shaking vigorously and allowing the layers to separate after each addition, until a permanent orange–pink colour is produced in the chloroform layer. Each mL of 0.004M *sodium dodecyl sulfate VS* is equivalent to 1.384 mg of $C_{19}H_{35}NO_2$,HCl.