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

Dicycloverine Oral Solution

General Notices

Action and use

Anticholinergic.

DEFINITION

Dicycloverine Oral Solution is a solution of Dicycloverine Hydrochloride in a suitable flavoured vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements.

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

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. To a volume containing 0.1 g of dicycloverine hydrochloride add 10 mL of *water* and 1 mL of *hydrochloric acid*, shake with 30 mL of *ether* and allow to separate. Extract the aqueous layer with 30 mL of *chloroform*, wash the extract with two 10 mL quantities of *water* and filter the chloroform solution through *anhydrous sodium sulfate*. Evaporate the filtrate to dryness, recrystallise the residue from hot *acetone* and dry the precipitate at 105° for 30 minutes. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of dicycloverine hydrochloride (*RS 098*).
B. Acidify the oral solution with 2M *nitric acid* and add *silver nitrate solution*. A white precipitate is produced.

TESTS

Related substances

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

(1) Add 10 mL of *water* and 1 mL of *hydrochloric acid* to a volume containing 0.1 g of dicycloverine hydrochloride, shake with 30 mL of *ether* and allow to separate. Extract the aqueous layer with 30 mL of *dichloromethane*, wash the extract with two 10 mL quantities of *water*, 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 as the coating *silica gel. G*
(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 it 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%).

Disregard any spot remaining on the line of application.

ASSAY

To a weighed quantity containing 5 mg of dicycloverine hydrochloride add 5 mL of *sulfuric acid (10%)* and 2 mL of 0.02M *potassium permanganate*, mix, allow to stand, add 20 mL of *water* and 20 mL of *chloroform* to the decolourised solution and titrate with 0.001M *sodium dodecyl sulfate VS* using 1 mL of *dimethyl yellow solution* as indicator. Each mL of 0.001M *sodium dodecyl sulfate VS* is equivalent to 0.3460 mg of $C_{19}H_{35}NO_2$,HCl. Determine the *weight per mL* of the oral solution, Appendix V G, and calculate the content of $C_{19}H_{35}NO_2$,HCl, weight in volume.

STORAGE

Dicycloverine Oral Solution should be protected from light.