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

Dimenhydrinate Tablets

General Notices

Action and use

Histamine H_1 receptor antagonist; antihistamine.

DEFINITION

Dimenhydrinate Tablets contain Dimenhydrinate.

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

Content of dimenhydrinate, $C_{17}H_{21}NO,C_7H_7ClN_4O_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 0.1 g of Dimenhydrinate with 10 mL of a mixture of equal volumes of *chloroform* and *ether* for 5 minutes, filter and evaporate the filtrate to an oily residue on a water bath. Add 3 mL of *ether* to the residue and scratch the interface between the residue and the ether gently with a glass rod until crystals appear in the liquid. Transfer the suspension of crystalline material in ether to a watch glass, allow the solvent to evaporate in a current of air and dry the residue at 60°. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of dimenhydrinate *(RS 104)*.

TESTS

Theophylline and substances related to diphenhydramine

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

(1) Shake a quantity of the powdered tablets containing 0.1 g of Dimenhydrinate with three 10-mL quantities of *chloroform*, filter, evaporate the combined filtrates almost to dryness and dissolve the residue in 5 mL of *chloroform*.
(2) Dilute 1 volume of solution (1) to 100 volumes with *chloroform*.
(3) 0.010% w/v of *theophylline* in *chloroform*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel GF_{254}*.
(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 cold air and examine under *ultraviolet light (254 nm)* (first examination). Spray the plate with *potassium iodobismuthate solution*, allow it to dry in air and spray with *hydrogen peroxide solution (10 vol)* and examine in daylight (second examination).

MOBILE PHASE

1 volume of 13.5M *ammonia*, 9 volumes of *methanol* and 90 volumes of *dichloromethane*.

LIMITS

In the first examination:

any spot corresponding to theophylline in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (3) (0.5%).

In the second examination:

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

Disregard any spot extending from the line of application to an Rf value of about 0.1.

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.1 g of Dimenhydrinate as completely as possible in 20 mL of *water*, add 10 mL of 5M *ammonia*, mix, extract with successive quantities of 15, 15, 15, 10 and 10 mL of *ether* and wash the combined extracts with 10 mL of *water*. Evaporate the ether, warm the residue with 10 mL of *ethanol (96%)* until dissolved, cool, add 50 mL of *0.01M hydrochloric acid VS* and titrate the excess of acid with *0.01M sodium hydroxide VS* using *methyl red mixed solution* as indicator. Each mL of *0.01M hydrochloric acid VS* is equivalent to 4.700 mg of $C_{17}H_{21}NO,C_7H_7ClN_4O_2$.