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

Hydralazine Tablets

General Notices

Action and use

Vasodilator; treatment of hypertension.

DEFINITION

Hydralazine Tablets contain Hydralazine Hydrochloride.

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

Content of hydralazine hydrochloride, $C_8H_8N_4,HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Dissolve a quantity of the powdered tablets containing 0.1 g of Hydralazine Hydrochloride in 10 mL of *water*, make alkaline with 2 mL of 5M *ammonia* and extract with two 10-mL quantities of *chloroform*. Combine the chloroform extracts and evaporate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of hydralazine *(RS 176)*.
B. Shake a quantity of the powdered tablets containing 25 mg of Hydralazine Hydrochloride with 30 mL of *methanol* for 15 minutes, add sufficient *methanol* to produce 50 mL and filter. Dilute 1 volume of the filtrate to 50 volumes with *water*. The *light absorption* of the resulting solution, Appendix II B, in the range 230 to 350 nm exhibits four maxima, at 240, 260, 305 and 315 nm.
C. Extract a quantity of the powdered tablets containing 0.1 g of Hydralazine Hydrochloride with two 25-mL quantities of *methanol*, filter the combined extracts and evaporate to dryness. To 5 mL of a 1% w/v solution of the residue in *methanol* add 5 mL of a 2% w/v solution of *2-nitrobenzaldehyde* in *ethanol (96%)*. An orange precipitate is produced.

TESTS

Hydrazine

Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel precoated plate (Merck silica gel 60 plates are suitable) and as the mobile phase the upper layer obtained by shaking together 20 volumes of 13.5M *ammonia*, 20 volumes of *ethyl acetate* and 80 volumes of *hexane* and allowing to separate. Apply separately to the plate 40 µL of each of the following solutions. For solution (1) extract a quantity of the powdered tablets containing 50 mg of Hydralazine Hydrochloride with 10 mL of 0.1M *methanolic hydrochloric acid*; to 2 mL add 1 mL of a 2% w/v solution of *salicylaldehyde* in *methanol* and 0.1 mL of *hydrochloric acid*, centrifuge and use the supernatant liquid. Prepare solution (2) in the same manner, but using 2 mL of a 0.00025% w/v solution of *hydrazine sulfate* in 0.1M *methanolic hydrochloric acid* in place of the solution of the substance being examined. After removal of the plate, allow it to dry in air and spray with *dimethylaminobenzaldehyde solution R1*. Any spot corresponding to hydrazine in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.05%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 50 mg of Hydralazine Hydrochloride add 50 mL of *water* and shake for 20 minutes. Add 60 mL of *hydrochloric acid* and titrate with *0.025M potassium iodate VS* determining the end point potentiometrically using platinum and calomel electrodes. Each mL of *0.025M potassium iodate VS* is equivalent to 4.916 mg of $C_8H_8N_4$,HCl.

STORAGE

Hydralazine Tablets should be protected from light.