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Phenelzine Tablets

General Notices

Action and use

Monoamine oxidase inhibitor; antidepressant.

DEFINITION

Phenelzine Tablets contain Phenelzine Sulfate. They are coated.

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

Content of phenelzine, $C_8H_{12}N_2$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the powdered tablets containing the equivalent of 30 mg of phenelzine with 25 mL of *water* for 5 minutes and filter. Make the filtrate alkaline with 5M *sodium hydroxide* and extract with two 25 mL quantities of *chloroform*. Extract the combined chloroform layers with two 25 mL quantities of 0.05M *sulfuric acid* and dilute the combined extracts to 100 mL with 0.05M *sulfuric acid*. The *light absorption* of the resulting solution, Appendix II B, in the range 230 to 350 nm exhibits three well-defined maxima, at 252, 258 and 263 nm.
B. Extract a quantity of the powdered tablets containing the equivalent of 30 mg of phenelzine with 10 mL of *water* and filter. Make 5 mL of the filtrate alkaline with 5M *sodium hydroxide* and add 1 mL of *cupri-tartaric solution R1*. A red precipitate is produced.
C. Extract a quantity of the powdered tablets containing the equivalent of 45 mg of phenelzine with 5 mL of *water* and filter. The filtrate yields the reactions characteristic of *sulfates*, Appendix VI.

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing the equivalent of 0.1 g of phenelzine add 20 mL of *water* and 2 mL of 2M *hydrochloric acid*, heat to boiling and boil for 30 seconds, stirring constantly. Add 25 mL of *water*, cool, add 2 g of *sodium hydrogen carbonate* and 50 mL of *0.05M iodine VS*, stopper the flask and allow to stand for 90 minutes. Add 15 mL of 2M *hydrochloric acid* and titrate with 0.1M *sodium thiosulfate VS* using *starch mucilage*, added towards the end of the titration, as indicator. Repeat the operation without the powder. The difference between the titrations represents the amount of iodine required. Each mL of *0.05M iodine VS* is equivalent to 3.405 mg of $C_8H_{12}N_2$.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of phenelzine.