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Dexamfetamine Tablets

General Notices

Action and use

Amfetamine.

DEFINITION

Dexamfetamine Tablets contain Dexamfetamine Sulfate.

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

Content of dexamfetamine sulfate, $(C_9H_{13}N)_2,H_2SO_4$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Dissolve a quantity of the powdered tablets containing 0.1 g of dexamfetamine sulfate as completely as possible in 20 mL of *water*, filter, add 2 mL of 5M *sodium hydroxide* and extract with three 25 mL quantities of *ether*, washing the combined extracts with 5 mL of *water*. To the ether solution add 10 mL of 0.05M *sulfuric acid* and shake well. The acid layer, after warming to dispel residual ether and cooling to 20°, is dextrorotatory.
B. Extract a quantity of the powdered tablets containing 50 mg of dexamfetamine sulfate with 10 mL of *water*, filter, cool to about 15°, add 3 mL of 1M *sodium hydroxide* and shake for 2 minutes with 1 mL of a mixture of 1 volume of *benzoyl chloride* and 2 volumes of *ether*. Filter, wash the residue with 15 mL of *water* and recrystallise twice from *ethanol (50%)*. The *melting point* of the crystals, after drying at 105° for 1 hour, is about 156°, Appendix V A.

ASSAY

Weigh and powder 20 tablets, or more if necessary. Dissolve a quantity of the powder containing 0.1 g of Dexamfetamine Sulfate as completely as possible in 20 mL of *water*, add 8 g of *sodium chloride* and 2 mL of 5M *sodium hydroxide* and extract with successive quantities of 50, 20, 20 and 20 mL of *ether*. Extract the combined ether extracts with four 10 mL quantities of 0.1M *hydrochloric acid* and make the combined acid extracts alkaline with 5M *sodium hydroxide*. Dilute to 120 mL with *water* and distil into 20 mL of *0.05M hydrochloric acid VS* until only 5 mL of liquid remains in the distillation flask. Boil, cool and titrate the excess of acid with *0.05M sodium hydroxide VS* using *methyl red solution* as indicator. Each mL of *0.05M hydrochloric acid VS* is equivalent to 9.212 mg of $(C_9H_{13}N)_2,H_2SO_4$.

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