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

Pentobarbital Tablets

General Notices

Action and use

Barbiturate.

DEFINITION

Pentobarbital Tablets contain Pentobarbital Sodium.

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

Content of pentobarbital sodium, $C_{11}H_{17}N_2NaO_3$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Heat 0.2 g of the residue obtained in the Assay on a water bath with the minimum quantity of *ethanol* (*25%*) until dissolved, filter while hot and allow the filtrate to cool. Filter, wash the crystals with a small quantity of *ethanol* (*25%*) and dry at 105°. The *infrared absorption spectrum* of the crystals, Appendix II A, is concordant with the *reference spectrum* of pentobarbital (*RS 264*).
B. The powdered tablets yield the reactions characteristic of *sodium salts*, Appendix VI.

TESTS

Isomer

Dissolve a quantity of the powdered tablets containing 0.3 g of Pentobarbital Sodium in 5 mL of a 5% w/v solution of *anhydrous sodium carbonate*, heating gently if necessary. Add 10 mL of a 3% w/v solution of *4-nitrobenzyl chloride* in *ethanol* (*96%*) and heat under a reflux condenser for 30 minutes. Cool to 25°, filter and wash the precipitate with five 5 mL quantities of *water*. Heat the precipitate with 25 mL of *ethanol* (*96%*) in a small flask under a reflux condenser until dissolved (about 10 minutes). Filter the hot solution, cool to 25° and, if necessary, scratch the side of the flask with a glass rod to induce crystallisation. Filter, wash the precipitate with two 5 mL quantities of *water* and dry at 100° to 105° for 30 minutes. The *melting point* of the dried precipitate is 136° to 148°, Appendix V A, Method I.

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.3 g of Pentobarbital Sodium as completely as possible in 10 mL of a 2% w/v solution of *sodium hydroxide*, saturate with *sodium chloride*, acidify with *hydrochloric acid* and extract with successive 15 mL quantities of *ether* until complete extraction is effected. Wash the combined extracts with two 2 mL quantities of *water* and extract the combined washings with 10 mL of *ether*. Add the ether to the main ether

layer, filter and wash the filter with *ether*. Evaporate the solvent and dry the residue to constant weight at 105°. Each g of residue is equivalent to 1.097 g of $C_{11}H_{17}N_2NaO_3$.