Quality standards

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

Pentobarbital Injection

General Notices

Action and use

Barbiturate.

DEFINITION

Pentobarbital Injection is a sterile¹ solution of Pentobarbital Sodium in a suitable vehicle.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of pentobarbital sodium, C₁₁H₁₇N₂NaO₃

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A clear, colourless or almost colourless solution.

IDENTIFICATION

- A. The <u>infrared absorption spectrum</u> of the residue obtained in the Assay, <u>Appendix II A</u>, is concordant with the <u>reference</u> spectrum of pentobarbital (<u>RSV 34</u>).
- B. Melting point of the residue obtained in the Assay, about 128°, Appendix V A.
- C. When introduced on a platinum wire into the flame of a Bunsen burner, imparts a yellow colour to the flame.

TESTS

Alkalinity

pH, 10.0 to 11.5, <u>Appendix V L</u>.

Isomer

To a volume containing 0.3 g of Pentobarbital Sodium diluted, if necessary, to 5 mL with <u>water</u>, add 0.3 g of <u>4-nitrobenzyl</u> <u>bromide</u> dissolved in 10 mL of <u>ethanol (96%)</u> and heat under a reflux condenser for 30 minutes. Cool to 25°, filter, wash the residue with four 5 mL quantities of <u>water</u> and transfer as completely as possible to a small flask. Add 25 mL of <u>ethanol (96%)</u> and heat under a reflux condenser for 10 minutes. The residue, after drying at 105° for 30 minutes, melts completely between 136° and 155°.

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ASSAY

To a volume containing 0.5 g of Pentobarbital Sodium diluted to 15 mL with <u>water</u> add 5 mL of $\underline{2M}$ <u>hydrochloric acid</u>, extract with 50 mL of <u>ether</u> and then with successive 25 mL quantities of <u>ether</u> until complete extraction is effected. Wash the combined extracts with two 5 mL quantities of <u>water</u> and wash the combined aqueous washings with 10 mL of <u>ether</u>. Add the ether to the main ether extract, evaporate to low volume, add 2 mL of <u>absolute ethanol</u>, evaporate to dryness and dry the residue to <u>constant weight</u> at 105°. Each g of residue is equivalent to 1.097 g of $C_{11}H_{17}N_2NaO_3$.

When pentobarbitone injection is prescribed or demanded, Pentobarbital Injection shall be dispensed or supplied.

1 Solutions containing 20% w/v of Pentobarbital Sodium in 100 mL and 500 mL quantities are also available for purposes other than injection; such solutions are not necessarily sterile but comply with all the other requirements of the monograph; they may be coloured.