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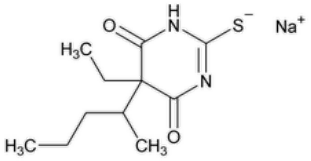
Thiopental Sodium



$C_{11}H_{17}N_2NaO_2S$ 264.32

4,6(1*H*,5*H*)-Pyrimidinedione, 5-ethyldihydro-5-(1-methylbutyl)-2-thioxo-, monosodium salt, (±)-;

Sodium (±)-5-ethyl-5-(1-methylbutyl)-2-thiobarbiturate CAS RN®: 71-73-8; UNII: 49Y44QZL70.

DEFINITION

Thiopental Sodium contains NLT 97.0% and NMT 102.0% of thiopental sodium ($C_{11}H_{17}N_2NaO_2S$), calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample: 500 mg of Thiopental Sodium

Analysis: Dissolve the *Sample* in 10 mL of water in a separator, add 10 mL of 3 N hydrochloric acid, and extract the liberated thiopental with two 25-mL portions of chloroform. Evaporate the combined chloroform extracts to dryness. Add 10 mL of ether, evaporate again, and dry at 105° for 2 h.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Thiopental RS.

• **B.** **Identification Tests—General**, *Sodium*⟨191⟩

Analysis: Ignite 500 mg.

Acceptance criteria: The residue meets the requirements.

• **C.**

Sample: 200 mg of Thiopental Sodium

Analysis 1: Dissolve the *Sample* in 5 mL of 1 N sodium hydroxide, and add 2 mL of lead acetate TS.

Acceptance criteria 1: A white precipitate is formed, and it gradually darkens when the mixture is boiled.

Analysis 2: Acidify the darkened mixture obtained from *Analysis 1* with hydrochloric acid.

Acceptance criteria 2: Hydrogen sulfide is evolved, and it is recognizable by its darkening of moistened lead acetate test paper held in the vapor.

ASSAY

• **Procedure**

Solution A: 4 g/L of sodium hydroxide

Standard solution: 5 µg/mL of USP Thiopental RS in *Solution A*

Sample solution: 5 µg/mL of Thiopental Sodium in *Solution A*

Instrumental conditions

Mode: UV

Analytical wavelength: 304 nm

Cell: 1 cm

Blank: *Solution A*

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of thiopental sodium ($C_{11}H_{17}N_2NaO_2S$) in the portion of Thiopental Sodium taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Thiopental RS in the *Standard solution* (µg/mL)

C_U = concentration of Thiopental Sodium in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of thiopental sodium, 264.32

M_{r2} = molecular weight of thiopental, 242.34

Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

• **Ordinary Impurities ⟨466⟩**

Standard solution: 9.2 mg/mL of USP Thiopental RS in methanol

Sample solution: 10 mg/mL of Thiopental Sodium in methanol

Application volume: 40 µL

Eluant: Toluene and methanol (85:15)

Visualization: 1

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 80° for 4 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Thiopental RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
THIOPENTAL SODIUM	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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