Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-25765A33-1831-4503-8DE9-7857AA21EAA3_4_en-US
DOI: https://doi.org/10.31003/USPNF_M82880_04_01
DOI Ref: we3v1

Thiopental Sodium for Injection

DEFINITION

Thiopental Sodium for Injection is a sterile mixture of Thiopental Sodium and anhydrous Sodium Carbonate as a buffer. It contains NLT 93.0% and NMT 107.0% of the labeled amount of thiopental sodium ($C_{11}H_{17}N_2NaO_2S$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Nominally 500 mg of thiopental sodium from Thiopental Sodium for Injection

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 those of a similar preparation of USP Thiopental RS.

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

Sample: Nominally 500 mg of thiopental sodium from Thiopental Sodium for Injection

Analysis: Ignite the *Sample*.

Acceptance criteria: The residue meets the requirements.

ASSAY

• **Procedure**

Diluent: 4 g/L of sodium hydroxide in water

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

Sample stock solution: Nominally 50 mg/mL of thiopental sodium from the contents of 10 containers of Thiopental Sodium for Injection dissolved in a sufficient volume of water

Sample solution: Nominally 5 µg/mL of thiopental sodium in *Diluent* from the *Sample stock solution*

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 304 nm

Cell: 1 cm

Blank: *Diluent*

Analysis

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

Calculate the percentage of the labeled amount of thiopental sodium ($C_{11}H_{17}N_2NaO_2S$) in the portion of Thiopental Sodium for Injection 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 the *Standard solution* (µg/mL)

C_U = nominal concentration of the *Sample solution* (µg/mL)

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

M_{r2} = molecular weight of thiopental, 242.34

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **Completeness of Solution ⟨641⟩**

Sample solution: Mix 800 mg of Thiopental Sodium for Injection with 10 mL of carbon dioxide-free water.

Acceptance criteria: After 1 min, the solution is clear and free from undissolved solid.

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 1.0 USP Endotoxin Unit/mg of thiopental sodium.

• **pH ⟨791⟩**

Sample solution: Use the *Sample solution* prepared in the test for *Completeness of Solution*.

Acceptance criteria: 10.2–11.2

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Other Requirements:** Meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

• **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 FOR INJECTION	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(1)

Current DocID: GUID-25765A33-1831-4503-8DE9-7857AA21EAA3_4_en-US

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