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Amobarbital Sodium for Injection

DEFINITION

Amobarbital Sodium for Injection is Amobarbital Sodium suitable for parenteral use. It contains NLT 98.5% and NMT 100.5% of the labeled amount of amobarbital sodium ($C_{11}H_{17}N_2NaO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

  Sample: Residue obtained in the *Assay*

  Acceptance criteria: Meets the requirements

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

  Sample: Nominally 200 mg of amobarbital sodium from Amobarbital Sodium for Injection

  Analysis: Ignite the *Sample*.

  Acceptance criteria: The residue effervesces with acid and meets the requirements of the tests.

ASSAY

- **Procedure**

  Sample solution: Transfer nominally 500 mg of amobarbital sodium from Amobarbital Sodium for Injection to a suitable separator, and dissolve in 15 mL of water. Add 2 mL of hydrochloric acid, and shake. Completely extract the amobarbital with 25-mL portions of chloroform. Combine the chloroform extractions, and pass through a glass filter funnel into a tared beaker. Wash the separator and the filter with several small portions of chloroform. Use the combined chloroform extractions and the washings.

  Test for completeness of extraction: Extract the remaining solution in the separator with an additional 10-mL portion of chloroform, and evaporate the solvent; NMT 0.5 mg of residue remains.

  Analysis: Evaporate the *Sample solution* on a steam bath with the aid of a current of air. Dry the residue at 105° for 30 min, cool, and weigh. Calculate the percentage of the labeled amount of amobarbital sodium ($C_{11}H_{17}N_2NaO_3$) in the portion of Amobarbital Sodium for Injection taken:

$$\text{Result} = (W_R/W_S) \times (M_{r1}/M_{r2}) \times 100$$

W_R = weight of the residue from the *Analysis* (mg)

W_S = nominal weight of amobarbital sodium in the *Sample solution* (mg)

M_{r1} = molecular weight of amobarbital sodium, 248.25

M_{r2} = molecular weight of amobarbital, 226.27

  Acceptance criteria: 98.5%–100.5% on the dried basis

PERFORMANCE TESTS

- Uniformity of Dosage Units ⟨905⟩: Meets the requirements

SPECIFIC TESTS

- Injections and Implanted Drug Products ⟨1⟩, *Specific Tests, Completeness and clarity of solutions*: At the time of use, it meets the requirements.
- Completeness of Solution ⟨641⟩

  Sample solution: 1 g of amobarbital sodium from Amobarbital Sodium for Injection in 10 mL of carbon dioxide-free water

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

- Loss on Drying ⟨731⟩

  Sample: 1 g

  Analysis: Dry the *Sample* at 105° for 4 h.

  Acceptance criteria: NMT 1.0%

- pH ⟨791⟩

  Sample solution: Nominally 100 mg/mL of amobarbital sodium from Amobarbital Sodium for Injection in carbon dioxide-free water

  Acceptance criteria: NMT 11.0

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- **Sterility Tests ⟨71⟩:** Meets the requirements
- **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.4 USP Endotoxin Units/mg of amobarbital sodium.
- **Other Requirements:** It 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 Amobarbital RS

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

Topic/Question	Contact	Expert Committee
AMOBARBITAL SODIUM FOR INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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