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Amobarbital Sodium

$C_{11}H_{17}N_2NaO_3$ 248.25

2,4,6(1*H*,3*H*,5*H*)-Pyrimidinetrione, 5-ethyl-5-(3-methyl butyl)-, monosodium salt.

Sodium 5-ethyl-5-isopentylbarbiturate CAS RN®: 64-43-7; UNII: G0313KNC7D.

» Amobarbital Sodium contains not less than 98.5 percent and not more than 100.5 percent of $C_{11}H_{17}N_2NaO_3$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

USP Reference standards ⟨11⟩—

USP Amobarbital RS

Completeness of solution ⟨641⟩—Mix 1.0 g with 10 mL of carbon dioxide-free water: after 1 minute, the solution is clear and free from undissolved solid.

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) : of residue obtained in the *Assay*.

B: Ignite about 200 mg: the residue effervesces with acid and responds to the tests for *Sodium* ⟨191⟩.

pH ⟨791⟩**:** not more than 11.0, in the solution prepared for the test for *Completeness of solution*.

Loss on drying ⟨731⟩—Dry about 1 g, accurately weighed, at 105° for 4 hours: it loses not more than 2.0% of its weight.

Other requirements—Where the label states that Amobarbital Sodium is sterile, it meets the requirements for *Sterility* and *Bacterial endotoxins* under *Amobarbital Sodium for Injection*. Where the label states that Amobarbital Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Amobarbital Sodium for Injection*.

Assay—Dissolve about 500 mg of Amobarbital Sodium, accurately weighed, in about 15 mL of water in a separator. To the solution add 2 mL of hydrochloric acid, shake, and completely extract the liberated amobarbital with 25-mL portions of chloroform. Test for completeness of extraction by extracting with an additional 10-mL portion of chloroform and evaporating the solvent: not more than 0.5 mg of residue remains. Filter the combined extract through a glass filter funnel into a tared beaker, and wash the separator and the filter with several small portions of chloroform. Evaporate the combined filtrate and washings on a steam bath with the aid of a current of air, dry the residue at 105° for 30 minutes, cool, and weigh. The weight of the residue, multiplied by 1.097, represents the weight of $C_{11}H_{17}N_2NaO_3$.

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

Topic/Question	Contact	Expert Committee
AMOBARBITAL SODIUM	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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