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Pentobarbital Sodium

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

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

Sodium 5-ethyl-5-(1-methylbutyl)barbiturate CAS RN®: 57-33-0; UNII: NJJ0475N0S.

» Pentobarbital Sodium contains not less than 98.0 percent and not more than 102.0 percent of $C_{11}H_{17}N_2NaO_3$, calculated on the dried basis.

Where the material is labeled as intended solely for veterinary use, Pentobarbital Sodium contains not less than 97.0 percent and not more than 102.0 percent of $C_{11}H_{17}N_2NaO_3$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Pentobarbital RS

Completeness of solution—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⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 10 µg per mL.

Medium: dilute ammonium hydroxide (1 in 200).

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

C: Ignite about 200 mg: the residue effervesces with acids, and meets the requirements of the tests for *Sodium ⟨191⟩*.

pH ⟨791⟩: between 9.8 and 11.0, in the solution prepared in the test for *Completeness of solution.*

Loss on drying ⟨731⟩—Dry it at 105° for 6 hours: it loses not more than 3.5% of its weight.

Related compounds—

Mobile phase—Prepare as directed in the *Assay.*

Standard solution—Dissolve an accurately weighed quantity of USP Pentobarbital RS in *Mobile phase,* and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.001 mg per mL.

Test solution—Transfer about 110 mg of Pentobarbital Sodium, accurately weighed, to a 100-mL volumetric flask, add about 80 mL of *Mobile phase,* and sonicate until dissolved. Dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 214-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the capacity factor, *k′,* is not less than 2.5; the column efficiency is not less than 15,000 theoretical plates; the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 15.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and *Test solution* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the percentage of any impurity in the portion of Pentobarbital Sodium taken by the formula:

$$(248.25/226.27)(10{,}000/F)(C/W)(r_i/r_S)$$

in which 248.25 and 226.27 are the molecular weights of pentobarbital sodium and pentobarbital, respectively; *F* is the relative response factor of the impurity according to the table below; *C* is the concentration, in mg per mL, of USP Pentobarbital RS in the *Standard solution; W* is the weight, in mg, of Pentobarbital Sodium, on the dried basis, used to prepare the *Test solution;* r_i is the peak area for any impurity in the *Test*

solution; and r_S is the peak area for pentobarbital in the *Standard solution:* the impurities meet the requirements given in the table below:

Compound Name	Relative Retention Time	Relative Response Factor	Limit (%)
6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid	about 0.39	1.5	0.2
5-Ethyl-5-(1-ethyl-propyl)barbituric acid*	about 0.93	1.0	0.1
Pentobarbital	1.0	—	—
5-Ethyl-5-(1,3-dimethylbutyl) barbituric acid	about 1.5	0.9	0.3
Unknown impurities	—	1.0	0.1
Total	—	—	0.5

* Where the material is labeled as intended solely for veterinary use, the limit of 5-ethyl-5-(1-ethylpropyl) barbituric acid is 3.0%.

Assay—

[NOTE—Use the value for *Loss on drying* obtained at the same time as the preparation of the *Test solution* in the test for *Related compounds* and the *Assay preparation* in the *Assay.*]

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as described in the *Assay* under *Pentobarbital.*

Assay preparation—Transfer about 110 mg of Pentobarbital Sodium, accurately weighed, to a 100-mL volumetric flask, add about 80 mL of *Mobile phase,* and sonicate until dissolved. Dilute with *Mobile phase* to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask. Dilute with *Mobile phase* to volume, and mix.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{11}H_{17}N_2NaO_3$ in the portion of Pentobarbital Sodium taken by the formula:

$$(248.25/226.27)1000C(r_U/r_S)$$

in which 248.25 and 226.27 are the molecular weights of pentobarbital sodium and pentobarbital, respectively; C is the concentration, in mg per mL, of USP Pentobarbital RS in the *Standard preparation;* and r_U and r_S are the peak areas obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
PENTOBARBITAL SODIUM	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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