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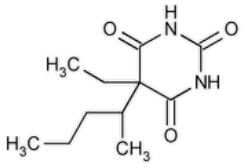
Pentobarbital

Change to read:



$C_{11}H_{18}N_2O_3$ ▲226.28▲ (USP 1-Aug-2024)

2,4,6(1*H*,3*H*,5*H*)-Pyrimidinetrione, 5-ethyl-5-(1-methylbutyl)-, (±)-;

(±)-5-Ethyl-5-(1-methylbutyl)barbituric acid;

▲(*RS*)-5-Ethyl-5-(pentan-2-yl)pyrimidine-2,4,6(1*H*,3*H*,5*H*)-trione▲ (USP 1-Aug-2024) CAS RN®: 76-74-4; UNII: I4744080IR.

DEFINITION

Pentobarbital contains NLT 98.0% and NMT 102.0% of pentobarbital ($C_{11}H_{18}N_2O_3$), calculated on the dried basis. Where the material is labeled as intended solely for veterinary use, Pentobarbital contains NLT 97.0% and NMT 102.0% of pentobarbital ($C_{11}H_{18}N_2O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** ▲197A▲ (USP 1-Aug-2024)

▲▲ (USP 1-Aug-2024)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Mobile phase: Acetonitrile and 0.01 M monobasic potassium phosphate (35:65). Adjust ▲with 25% (v/v) phosphoric acid solution to a pH of 3.5▲ (USP 1-Aug-2024) .

Standard solution: 0.1 mg/mL of USP Pentobarbital RS in *Mobile phase*

▲▲ (USP 1-Aug-2024)

Sample solution: ▲0.1 mg/mL of Pentobarbital in *Mobile phase*. Sonicate to dissolve if necessary.▲ (USP 1-Aug-2024)

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 1.8 times the retention time of pentobarbital▲ (USP 1-Aug-2024)

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲ (USP 1-Aug-2024)

Tailing factor: NMT 1.5

Relative standard deviation: NMT ▲0.73%▲ (USP 1-Aug-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pentobarbital ($C_{11}H_{18}N_2O_3$) in the portion of Pentobarbital taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak ▲response of pentobarbital▲ (USP 1-Aug-2024) from the *Sample solution*

r_S = peak ▲response of pentobarbital▲ (USP 1-Aug-2024) from the *Standard solution*

C_S = concentration of USP Pentobarbital RS in the *Standard solution* (mg/mL)

C_U = concentration of Pentobarbital in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% ▲▲ (USP 1-Aug-2024) on the dried basis; and 97.0%–102.0% ▲▲ (USP 1-Aug-2024) on the dried basis, where the material is labeled as intended solely for veterinary use

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Change to read:

• **Organic Impurities**

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

Standard solution: 0.001 mg/mL of USP Pentobarbital RS in *Mobile phase*

▲Sensitivity solution: 0.0005 mg/mL of USP Pentobarbital RS from the *Standard solution*, in *Mobile phase*▲ (USP 1-Aug-2024)

Sample solution: 1 mg/mL of Pentobarbital in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

▲Run time: NLT 2.0 times the retention time of pentobarbital▲ (USP 1-Aug-2024)

System suitability

Samples: *Standard solution* ▲and *Sensitivity solution*

[Note—The relative retention times in *Table 1* are provided as information that could aid in peak assignment.]

Table 1▲ (USP 1-Aug-2024)

Name	Relative Retention Time
▲Pentobarbital imino analog[a]▲ (USP 1-Aug-2024)	0.39
▲Pentobarbital ethyl analog[b]▲ (USP 1-Aug-2024)	0.93
Pentobarbital	1.0
▲Pentobarbital isopropyl analog[c]▲ (USP 1-Aug-2024)	1.5

[a] 6-Imino-5-ethyl-5-(1-methylbutyl)barbituric acid.

[b] 5-Ethyl-5-(1-ethylpropyl)barbituric acid.

[c] 5-Ethyl-5-(1,3-dimethylbutyl)barbituric acid.

Suitability requirements

▲▲ (USP 1-Aug-2024)

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT ▲5.0%, ▲ (USP 1-Aug-2024) *Standard solution*

▲**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲ (USP 1-Aug-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any ▲specified and unspecified▲ (USP 1-Aug-2024) impurity in the portion of Pentobarbital taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak ▲response of any specified or unspecified▲ (USP 1-Aug-2024) impurity from the *Sample solution*

r_S = peak ▲response of▲ (USP 1-Aug-2024) pentobarbital from the *Standard solution*

C_S = concentration of USP Pentobarbital RS in the *Standard solution* (mg/mL)

C_U = concentration of Pentobarbital in the *Sample solution* (mg/mL)

F = relative response factor of the impurity (see ▲*Table 2*▲ (USP 1-Aug-2024))

Acceptance criteria: See ▲*Table 2*. The reporting threshold is 0.05%.

Table 2▲ (USP 1-Aug-2024)

Name	Relative Response Factor	Acceptance Criteria, NMT (%)
▲Pentobarbital imino analog▲ (USP 1-Aug-2024)	1.5	0.2
▲Pentobarbital ethyl analog▲ (USP 1-Aug-2024) [a]	1.0	0.1
▲▲ (USP 1-Aug-2024)	▲▲ (USP 1-Aug-2024)	▲▲ (USP 1-Aug-2024)
▲Pentobarbital isopropyl analog▲ (USP 1-Aug-2024)	0.9	0.3
▲Any unspecified impurity▲ (USP 1-Aug-2024)	1.0	0.1
Total ▲impurities▲ (USP 1-Aug-2024)	—	0.5

[a] Where the material is labeled as intended solely for veterinary use, the limit of ▲pentobarbital ethyl analog▲ (USP 1-Aug-2024) is ▲NMT▲ (USP 1-Aug-2024) 3.0%.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Pentobarbital RS

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

Topic/Question	Contact	Expert Committee
PENTOBARBITAL	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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